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TECHNICAL NOTES

Vaccine Safety Surveillance Tool

Updated: February 2024

Introduction

This document accompanies the Vaccine Safety Surveillance Tool.

The purpose of this document is to provide:

- background information on Canada's vaccine safety system and public health surveillance of adverse events following immunization (AEFIs) in Ontario
- an explanation of data extraction and analytic methods used for the tool
- technical notes on interpretation and limitations of AEFI surveillance data presented in the tool

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Adverse events reported following COVID-19 vaccine are not included in this tool; for COVID-19 vaccine associated AEFIs, see the surveillance report on AEFIs for COVID-19 in Ontario.

Canada's Vaccine Safety System

In Canada, vaccines are thoroughly reviewed for efficacy and safety prior to being approved for use. Following approval of a new vaccine, vaccines are highly regulated to ensure safety.[1] Post-marketing surveillance is initiated to ensure the ongoing monitoring of safety in the population receiving the vaccine.[2] Vaccine manufacturers are also required to adhere to internationally accepted standards of manufacturing to ensure quality and consistency. In addition, all lots of vaccine are subject to Health Canada's lot release program, which specifies standards for the production of each lot that must be met before sale in Canada.[2]

Post-marketing vaccine safety 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.[3] PHAC and Health Canada coordinate post-marketing surveillance nationally, while provinces and territories coordinate surveillance of adverse events following immunization (AEFIs) occurring within their jurisdiction in collaboration with local partners. Individual case reports of AEFIs represent an important source of data because they have the potential to identify previously unrecognized or rare AEFIs, as well as an increase in frequency or severity of known AEFIs, which can be further evaluated.[4] AEFIs reported to provincial and territorial public health authorities are reported to the Canadian Adverse Event Following Immunization Surveillance System (CAEFISS), maintained by PHAC. CAEFISS is a collaborative post-marketing surveillance system that continuously monitors the safety of vaccines in Canada. AEFI reports received by vaccine manufacturers may also be voluntarily

reported to CAEFISS; however, any serious reports received directly by the manufacturers are required by law to be reported to Health Canada. Reports of adverse events that must be reported by manufacturers to Health Canada include serious adverse reactions that are reported in Canada, unexpected serious adverse reactions reported in other countries, and unusual failures in efficacy for new drugs/vaccines in Canada. As part of vaccine safety surveillance at the national level, the Advisory Committee on Causality Assessment (ACCA) reviews select reports of AEFIs to determine whether an event was likely to have been causally related to a given vaccine.[5]

An AEFI (adverse event following immunization) is defined as any untoward medical occurrence that follows immunization and does not necessarily have a causal relationship with the vaccine. The adverse event may be any unfavourable or unintended sign, laboratory finding, symptom or disease.[2]

The National Advisory Committee on Immunization (NACI) independently reviews the available evidence on safety and efficacy of vaccines.[6] It also makes recommendations for the use of currently or newly approved vaccines in Canada, including identification of groups at risk for vaccine-preventable disease for whom vaccine programs should be targeted, as well as groups for whom the vaccine is contraindicated or should be used with precaution.

Public Health Surveillance of AEFIs in Ontario

The main objective of public health surveillance of AEFIs in Ontario is early detection and timely response to real or perceived vaccine safety signals or issues in order to help mitigate any impact on the health of individuals and maintain public confidence in vaccine programs. A robust vaccine safety surveillance system also provides important data to support provincial immunization program planning and evaluation.

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). The Health Protection and Promotion Act, RSO 1990, c. H.7, Section 38 mandates all health care providers who administer immunizations to report AEFIs for all vaccines authorized for use in Canada.[7] Once PHUs receive initial reports of AEFIs, reports are investigated, assessed and documented according to provincial surveillance guidelines.[9] AEFIs are then reported in the integrated Public Health Information System (iPHIS), the provincial electronic reporting system for diseases of public health significance and AEFIs. In early 2023, the Public Health Case and Contact Management Solution (CCM) replaced iPHIS as the electronic reporting system for all AEFIs. AEFI reports are required to be reported in iPHIS/CCM within five business days of receipt of initial notification to a PHU.[10,11]

Public Health Ontario (PHO) conducts provincial surveillance of AEFIs using the AEFI data entered into iPHIS/CCM by the PHUs. Through routine data extraction and analysis, PHO monitors for potential signals and investigates any potential vaccine safety issues. PHO also provides advice and support for local PHUs in the investigation and management of AEFI reports. The Ministry of Health is responsible for public health legislation and standards, which enable the reporting and collection of information required for provincial surveillance. PHO also transmits AEFI data to PHAC on a monthly basis for inclusion in CAEFISS, the national database containing AEFIs reported from all provinces and territories in Canada.

For more detailed information on vaccine safety surveillance in Ontario, including previous annual reports (in PDF format), please see PHO's Vaccine Safety web page.[12]

Data Extraction and Analysis

Data Sources and Extraction

AEFI data included in this tool were extracted from iPHIS on August 1, 2023. Population data are received from intelliHEALTH Ontario via the MOH and include estimates for 2012 to 2021 and projections for 2022. Population estimates and population projections data were received on May 10, 2023. Doses distributed are estimated using vaccine distribution data extracted on June 6, 2023 from the Digital Health Immunization Repository, 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.

The number of AEFI reports during the COVID-19 pandemic (2020-2022) should be interpreted with caution due to the potential impact on AEFI reporting, investigation and data entry arising from deferred routine immunization services, diminished health care seeking behaviours as a result of COVID-19 public health measures, decreased reporting from HCPs, as well as diversion of public health resources to the pandemic response.

Data Analysis

AEFI reports with a case classification of "confirmed" (i.e., meets the provincial AEFI surveillance definition) and associated with at least one active immunizing agent administered between 2012 and 2022 were included in the tool. Adverse events reported following COVID-19 vaccine are not included in this tool; for COVID-19 vaccine associated AEFIs, see the surveillance report on AEFIs for COVID-19 in Ontario. It is important to note that this tool describes adverse events that were temporally associated and not necessarily causally linked to vaccines.

The following AEFI reports were excluded from the analysis:

- AEFI reports with a case classification other than "confirmed" or a disposition of "does not meet definition," "entered in error" or "closed- duplicate – do not use" in iPHIS
- AEFI reports that are only associated with diagnostic agents (e.g., tuberculin skin test) and/or passive immunizing agents (e.g., immune globulin), with no active immunizing agents administered at the same time. These reports are not within the scope of provincial AEFI surveillance.[9]
- AEFI reports in non-residents of Ontario
- AEFI reports with a vaccine administration date not occurring between January 1, 2012 and December 31, 2022

Based on the provincial AEFI surveillance definitions are described in Appendix 1 of the Ontario Public Health Standards (OPHS), a confirmed AEFI report is defined as:

- Any untoward medical occurrence in a vaccine recipient which follows immunization that cannot be clearly attributed to other causes. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. A causal relationship with the administration of the vaccine does not need to be established in order to be reported as a confirmed case.[9]

Calculation of AEFI Reporting Rates

AEFI reporting rates are calculated using either doses distributed or population-based denominators, depending on the purpose and the availability of information. Doses distributed is used as a proxy for doses administered and enables a more accurate comparison of AEFI reporting rates across geographic areas by taking into account the differences in vaccine distribution. 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. 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 Geography section, as well as in the Vaccine section.

Since dose distribution data are not available within specific demographic groups (e.g., age groups, sex), population-based rates are used for calculating reporting rates within specific demographic groups. Population-based reporting rates are calculated using the number of AEFI reports by year of vaccine administration within a specific demographic group divided by the annual population of the same demographic group. 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 Geography sections.

See the section on General Limitations of AEFI Surveillance Data for more information on denominators used to calculate reporting rates.

Vaccine Safety Surveillance Tool

Trends

Temporal trends in the number of AEFI reports and reporting rate are assessed by year of vaccine administration. Trends can be viewed for Ontario or for each individual PHU. The number of AEFI reports during 2020-2022 should be interpreted with caution due to the potential impact on AEFI reporting, investigation and data entry arising from deferred routine immunization services, diminished health care seeking behaviours as a result of COVID-19 public health measures, decreased reporting from HCPs, as well as diversion of public health resources to the pandemic response.

Age and Sex

Number of AEFI reports and population-based reporting rates for the province are available by age and sex for each year.

AGE

Age categories for analysis are selected 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/other gender

(including gender other than male or female) are excluded from sex-specific analysis, but are included in the 'all sexes' category, and indicated in footnotes where relevant.

Geography

PHU-specific reporting rates are available in the form of a map, graph or data table. In the map, rates are grouped into four categories using quartiles (i.e., 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. COVID-19 vaccines are excluded from the tool.

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/HPV-9 (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, Pneu-C-13, MMR, Men-C-C, Var, and Rot-1/Rot-5 (Rot-5 replaced Rot-1 in 2018 and then Rot-1 replaced Rot-5 in mid-2021). 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 vaccine 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.[14] 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.[14] 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.[15] Due to the data limitations of passive surveillance, serious AEFIs are operationally defined in Ontario as those with in-patient hospitalization or are reported to have died. In-patient hospitalization is defined as having a hospitalization record with a discharge date that is at least one day following the admission date. Persistent or significant disability/incapacity and congenital anomaly/birth defect, are not systematically captured due to the relatively brief follow-up period of AEFIs reported in Ontario.

Adverse Events

An AEFI report refers to a report received by the PHU which pertains to one individual vaccine recipient who experiences one or more adverse events that are temporally associated (i.e., the event occurs after administration of the vaccine) with receipt of one or more vaccines administered at the same time (i.e., during the same day). One individual may have multiple AEFI reports if they experience adverse events following multiple doses in a series of different vaccines administered on different days. The definition of each adverse event is outlined in Appendix 1 (Adverse Events Following Immunization) of the Ontario Public Health Standards, Infectious Diseases Protocol, 2023.[9]

Adverse events are presented both individually and within event categories, based on the provincial surveillance definitions and categories.[9] 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 Data

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. 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 at a population level is not possible; further study would be required.

A further limitation of the analysis of AEFI surveillance data in Ontario is the lack of a population-based provincial immunization registry to estimate the number of individuals who were immunized or doses administered to individuals. This would enable estimation of AEFI incidence rates, including specific events, by vaccine type. In lieu of this, AEFI reporting rates are estimated using either the entire population irrespective of immunization status or vaccine doses distributed as the denominator. In this analysis, population-based denominators are used for overall system reporting rates (all vaccines combined) and for overall demographic analysis. This approach enables comparison of overall AEFI reporting trends over time and across geographic areas; however, population-based reporting rates have limitations as a proxy for true AEFI incidence where there are variations in vaccine uptake (i.e.,

coverage) over time or between geographic areas. Doses distributed are widely used in analyses of passive AEFI surveillance systems and can be a reasonable proxy for doses administered for established programs with known vaccine wastage.[16,17] When the amount of wastage is unknown and underestimated, this can result in underestimates of reporting rates. Additionally, in the context of new or discontinued vaccines/programs, the AEFI reporting rate using doses distributed as the denominator can be temporarily rendered invalid due to fluctuations in vaccine distribution caused by stockpiling, delayed vaccine use or large returns of unused/expired doses.

There have been substantial changes to AEFI surveillance in the province since 2012, including revised case definitions, updates to the iPHIS application, and changes to the publicly-funded immunization programs. The updates to case definitions and iPHIS have resulted in improvements to vaccine safety data quality but also impact comparability of AEFI surveillance data and analyses of trends over time. Therefore, to facilitate comparisons over time, in-depth trend analysis is limited to AEFIs following vaccines administered on or after January 1, 2012. In addition, trends in reported AEFIs can be influenced by changes to the publicly-funded program such as changes in vaccine products. Finally, the COVID-19 pandemic significantly reduced the number of AEFI reports received during 2020-2022. The number of AEFI reports during 2020-2022 should be interpreted with caution due to the potential impact on AEFI reporting, investigation and data entry arising from deferred routine immunization services, diminished health care seeking behaviours as a result of COVID-19 public health measures, decreased reporting from HCPs, as well as diversion of public health resources to the pandemic response.

How to Cite This Tool

Generic Citation

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Title of tool in sentence case [Internet]. Toronto, ON: King's Printer for Ontario; cYYYY [modified YYYY Mon DD; cited YYYY Mon DD]. Available from: [URL]

Example Citation

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Vaccine safety surveillance tool [Internet]. Toronto, ON: King's Printer for Ontario; 2024 [cited 2024 Jan 16]. Available from: https://www.publichealthontario.ca/en/Data-and-Analysis/Infectious-Disease/Vaccine-Safety#/trends

Source Statement for a Graph

Generic Citation

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

Example Citation

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Vaccine safety surveillance: number of AEFI reports and AEFI reporting rate in Ontario, 2012-22 [Internet]. Toronto, ON: King's Printer for Ontario; 2023 [cited 2023 Dec 16].

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

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

Example Citation

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Vaccine safety surveillance: reporting rate of AEFIs in Ontario – all vaccines, 2022 [Internet]. Toronto, ON: King's Printer for Ontario; 2023 [cited 2023 Dec 16].

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

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: King's Printer for Ontario; Year [cited date].

Example Citation

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, 2022 [Internet]. Toronto, ON: King's Printer for Ontario; 2023 [cited 2023 Dec 16].

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.

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