



**VACCINE
CHOICE**
CANADA
FORMERLY VRAN

Email: info@vaccinechoicecanada.com
Mail: P.O. Box 169, Winlaw, BC, V0G 2J0
Web site: www.vaccinechoicecanada.com

February 28, 2018
by email and Canada Post

To: Minister of Health Ginette Petitpas Taylor
House of Commons
Ottawa, Ontario
K1A 0A6
Ginette.PetitpasTaylor@parl.gc.ca

Dear Minister of Health Taylor,

Vaccine Choice Canada is deeply concerned that the public reporting of adverse events by both PHAC and MedEffect™ Canada are for unexplained reasons in hiatus. We appeal to you to look into this matter and explain why this hiatus has occurred as it directly affects the ability of the Canadian public to make informed decisions regarding vaccines.

Two entities in Canada's Health Portfolio collect reports on AEFIs—adverse events following immunization—and release public reports on the data. The Public Health Agency of Canada (PHAC) monitors adverse events through the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) and MedEffect™ Canada within Health Canada monitors adverse events through the Canada Vigilance Program. Health Canada oversees both of these programs.(1)

BACKGROUND

The collection of adverse event reports to biologics (vaccines) marketed in Canada is the basis of Canada's post-market surveillance system on vaccine safety.

As PHAC explains:

“The Public Health Agency of Canada collects case reports on adverse events following immunization from provincial and territorial health departments, health care professionals and the pharmaceutical industry.

The data is stored in the Canadian Adverse Events Following Immunization (CAEFI) database and is used to signal adverse events that may require more in-depth investigation. The main function of the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is to ensure the continued safety of vaccines on the Canadian market by monitoring adverse events following immunization with vaccines.“ Source: <https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>

As MedEffect™ further explains:

“All health products carry risks and benefits. Many of these risks are identified in pre-market testing and can be managed as “expected” or “tolerable” side effects that are outweighed by the product's benefits. However, once a product is made available on the Canadian market, new “unexpected” or undesirable side effects, referred to as adverse reactions, are sometimes discovered when the product is used in “real world” conditions...Most often, adverse reactions are unexpected and are not necessarily indicated on the product label or on any other information provided with the product.”

“Having the ability to track such adverse reactions is therefore critical to assessing and communicating the evolving pattern of risks associated with various health products. The only way to achieve this is if Canadians—health professionals and patients/consumers alike—report adverse reactions to Health Canada.”

Source: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/medeffect-canada.html#a3>

Ontario Public Health is even more specific on why adverse event reporting is so important to vaccine safety:

“Provincial reporting of AEFIs is an important component of the overall safety assessment of any vaccine. This type of surveillance, commonly called post-marketing or post-licensure surveillance, allows for monitoring of the vaccines throughout implementation in the context of “scaled up” vaccine production and expansion of the population receiving the vaccine.

“Individual case reports of AEFIs represent an important source of data as they have the potential to generate

signals of adverse reactions not previously recognized in clinical studies which can be further evaluated. This is particularly important for rare adverse events which may not have been evident in clinical trials due to limited sample size.” Source; Page 2, http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/aeft_cd.pdf

We can surmise from these quotes that the reporting and publication of post-market adverse event data, especially serious adverse event data, is information that Canadians should have access to. As you can see by the attached 2-page document, vaccine safety is of particular concern to parents since most serious adverse events are experienced by healthy babies and children.

REPORT TIMELINES

The last published quarterly report from PHAC’s CAEFISS was for the third quarter of 2016. The last published quarterly report from MedEffect’s Canada Vigilance (CV) Program was for the fourth quarter of 2016.

In the past, the quarterly reports on adverse events from both agencies were published on a regular and dependable schedule. Although the time period between collection and publication of Canadian data was 2 to 3 times longer than the USA reporting system VAERS—VAERS 3-month time lag, CV 5-month time lag, CAEFISS 9-month time lag—at least the publication schedule was regular. It is now 2 months into the first quarter of 2018 and we have seen no publication of AEFI data for the entire year of 2017 and in the case of CAEFISS for the final quarter of 2016. That particular time lag is now 14 months and counting.

We have inquired by email to both entities regarding this hiatus in published reports. Six months ago we received assurances from PHAC that both the 4th Quarter 2016 CAEFISS report and an annual 3-year summary report (for 2013–2015) would be published “shortly”. When no publications were seen on their website, we inquired again in mid-February and were assured again the 4th Quarter 2016 report would be published “soon” and that the 3-year summary report was scheduled for publication in April of 2018. We have not yet received a reply from MedEffect to our recent email inquiring why no reports have been published for the last 6 months when they normally publish every 3 months.

Most importantly however, our questions regarding policy or other changes that have led to this hiatus of publishing quarterly vaccine adverse event reports from both sources have gone unanswered.

Perhaps there is a simple explanation for this hiatus. We would greatly appreciate the Minister of Health looking into this and replying to our concerns in a timely manner.

Sincerely,

Nelle Maxey,

Vaccine Choice Canada Board Member on behalf of the Board of Directors

Footnote (1): See The Public Health Agency of Canada Act which defines PHAC as a Legislated Service Agency (LSA) and LSAs as follows [Emphasis ours]: “LSAs are:

- **headed by a CEO that reports to the Minister;**
- supported by a “Board” whose members are Governor-in-Council appointees;
- **subject to ministerial discretion;**
- separate employers under the Public Service Staff Relations Act (which increases the staffing authority and flexibility of the agency);
- focused on performance;
- provided with greater financial and administrative authorities than traditional departments; and
- overseen by the Auditor General of Canada.”

Attachment:

2-page Nutshell Summary of 2015 adverse event reports from the Canada Vigilance (CV) database and the CAEFISS database. The PDF of the entire Report (including this Nutshell summary) is available on our website at <https://vaccinechoiccanada.com/wp-content/uploads/Vaccine-Safety-Report-2-20B29E.pdf>

Vaccine Safety Report 2: 2015 Results in a Nutshell

The Vaccine Choice Canada investigations into Canada's **dual adverse events databases** began in the winter of 2015. This is our 4th report. Our three previous reports and this latest report are found on our website (at www.vaccinechoicecanada.com on the main menu: About Vaccines/General Issues/Reports).

The two separate databases we investigate are the Canada Vigilance or CV database and the CAEFISS or Canadian Adverse Events Following Immunization Surveillance system.

An AEFI is "any untoward medical occurrence which follows immunization". An SAE or Serious Adverse Event is one that results in death, a life threatening incident, hospitalization, disability or congenital deformity. These life-changing events are of the greatest concern to us.

Health professionals who administer vaccines file adverse events reports with database administrators. **The reporting rate is only 1% to 10% of ACTUAL adverse events occurring in the Canadian population.** Database administrators issue Quarterly Reports. Below are details teased from 2015 Quarterly Reports for both databases.

2015 Total: 522 SAE from both Canadian Databases

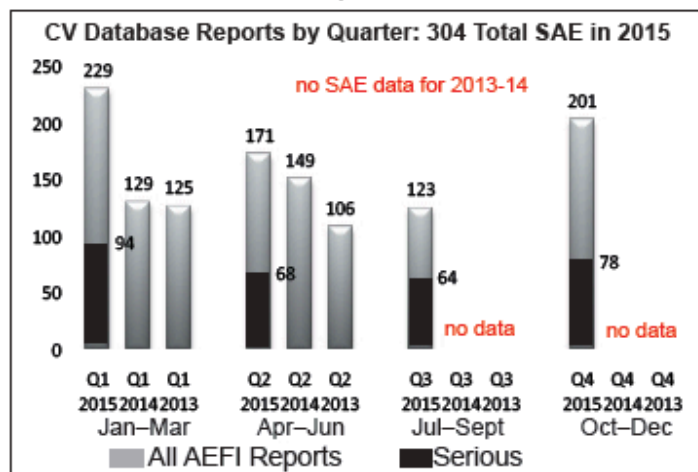
CAEFISS had 218 SAE reports and the CV database had 304.

- At a 1% reporting rate this means 52,200 Canadians experienced SERIOUS adverse events.
- At a 10% reporting rate this means 5,220 Canadians experienced SERIOUS adverse events.

2015 CAEFISS information and interpretations are based on only 42% of SAE reports in Canada. The other 58% from the CV database we have no detail on including age groups affected, suspect vaccines, or reporting sources for the serious events noted.

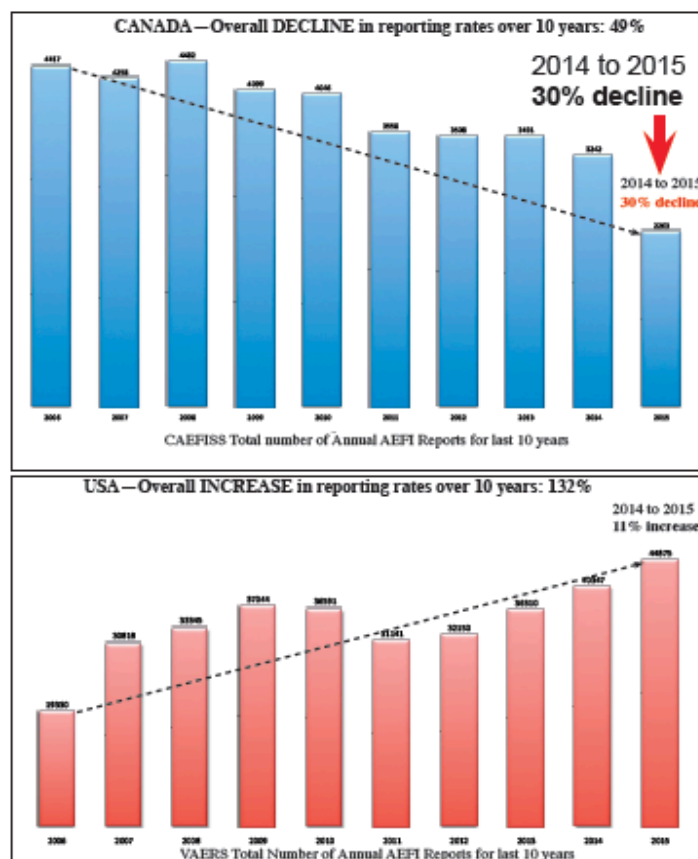
CV Database reports lack comparative data

The graphic below shows the available CV data. The Q3 and Q4 reports did not include historical data as Q1 and Q2 reports did. No historical data on SAEs was included in any report. Therefore no trends can be tracked. Finally, there was no annual data in Q4 report.



Canadian Adverse Event Reporting Rates Continue to Decline

Our graphic shows the declining reporting rates for CAEFISS adverse events in Canada compared to the increasing reporting rate in the USA.



Doctors Reporting Rate is Declining

CAEFISS Quarterly reports do not give reporting source data. However the 2014 Ontario Vaccine Safety Report shows doctors were reporting fewer adverse events for 3 years running: a 10% drop in number of reports in fact.

Figure 5. Percent distribution of AEFIs by reporting source, 2012-14

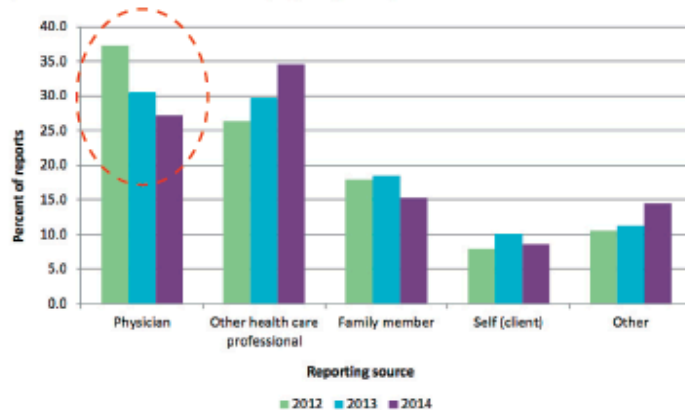


Table 2 from the Ontario report emphasizes the importance of doctor reporting. From the data given it appears Ontario doctors administer approximately 2 million

vaccines to children under 4 years of age in Ontario every year. **This is the age group that experiences the most number of serious adverse events.** Declining reporting rates by doctors is thus extremely worrying as they are the main source for adverse event data for this age group.

Table 2. Counts and reporting rates of AEFIs for school-administered and primary care-administered vaccines, 2012-14

Reporting source	2014		2013		2012	
	Count	Reporting rate (per 100,000 doses ³ distributed)	Count	Reporting rate (per 100,000 doses ³ distributed)	Count	Reporting rate (per 100,000 doses ³ distributed)
School-administered vaccines ¹	89	15.1	115	20.3	103	19.5
Primary care-administered vaccines ²	110	5.6	122	6.0	101	4.9

¹ AEFI reports for adolescents between 11 & 17 years of age following **School Administered** vaccines for Meningitis C, Hepatitis B and HPV

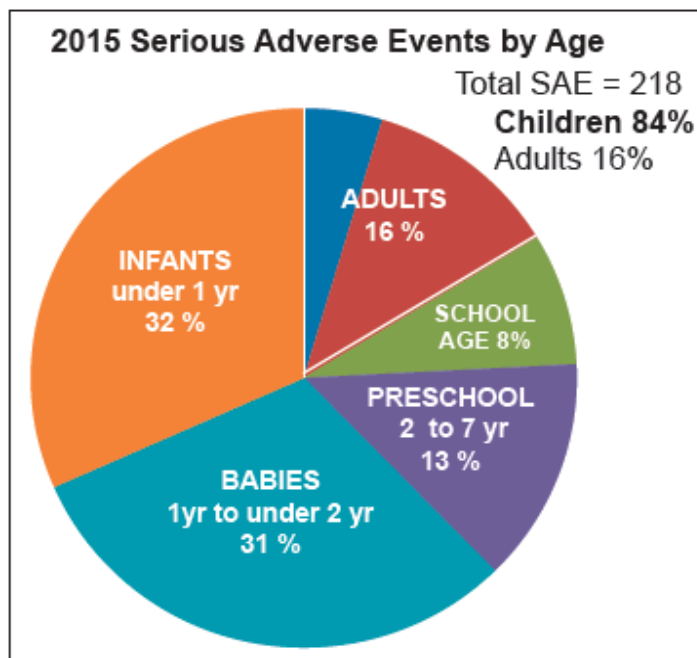
² AEFI Reports for Children less than 4 years of age following **Primary Care Administered** vaccines for DTap-IPV-Hib, Pneumonia C-13, Rotavirus, Meningitis C and MMR+V

Children Continue to Bear the Brunt of SAEs

The graphic below was created using the annual data collected from Table 1 in the four 2015 CAEFISS Quarterly reports. Unfortunately, the percent of Serious Events continues to rise for children.

In 2014 children of all ages experienced 80% of SAEs. In 2015 this had risen to 84%. In 2014 babies and infants under the age of 2 experienced 60% of SAEs. In 2015 this had risen to 63%. (The 5-year comparative chart is found on page 9 in this report.)

The only good news was that infants under 1 year of age experienced a decrease in serious adverse events. In 2015 there were only 68 SAEs reported for this age group. In 2014 there were 78. The Q4 CAEFISS report comments on fewer SAEs for infants in the last quarter saying, it “may be coincidental.” Whatever that means.

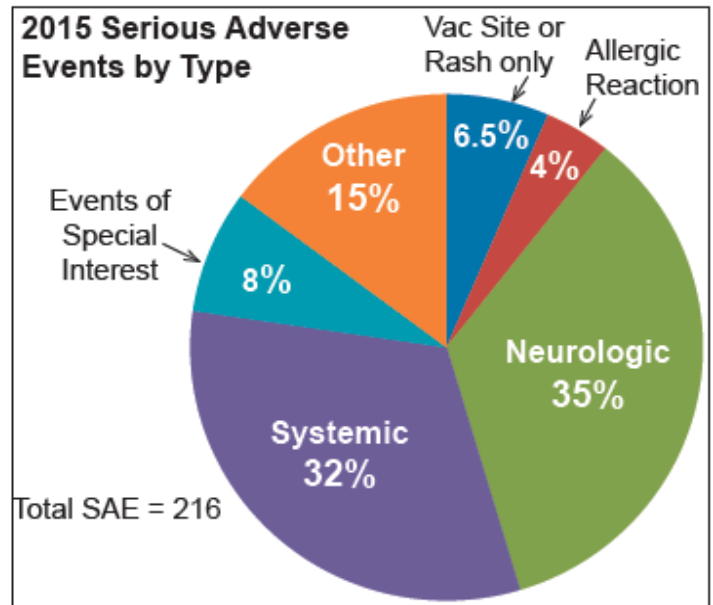


Children Experienced 84% of these Serious Events

The graphic below was created from Table 2 in the four 2015 CAEFISS Quarterly reports. Table 2 shows the main type of event experienced that caused the filing of the SAE report.

Starting at the top of the chart, number of events and very simple explanations of events are as follows:

- Vaccination site events which are serious include swelling of a limb where vaccine was given, cellulitis (skin infection), nodule formation at site—11 SAEs
Rash only means rash without a fever or other complications—3 SAEs
- Allergic or allergic-like reactions include respiratory problems or skin reactions like hives—9 SAEs
- Neurologic events, usually seizures, but can include permanent brain damage or GBS—75 SAEs
- Systemic events involve more than one system such as fever accompanied by severe vomiting and/or diarrhea or fainting with injury resulting —69 SAEs



- Events of special interest are **safety signals**. They include Arthritis, HHE, intussusception, para/anesthesia, parotitis, persistent crying, and thrombocytopenia—17 SAEs
- Other events are those listed on CAEFISS Report forms. They include gastro-intestinal reaction, arthralgia, SIDS/SUDS, vaccination failure, and undefined other events. Note that Sudden Infant Death Syndrome (SIDS) and Sudden Unexplained Death Syndrome (SUDS) data are not broken out in the reports—32 SAEs

In fact deaths are rarely mentioned in any of the CAEFISS reports. When they are mentioned, they are reported as caused by a “pre-existing condition” or unexplained causes. CAEFISS never attributes death to suspect vaccines.