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

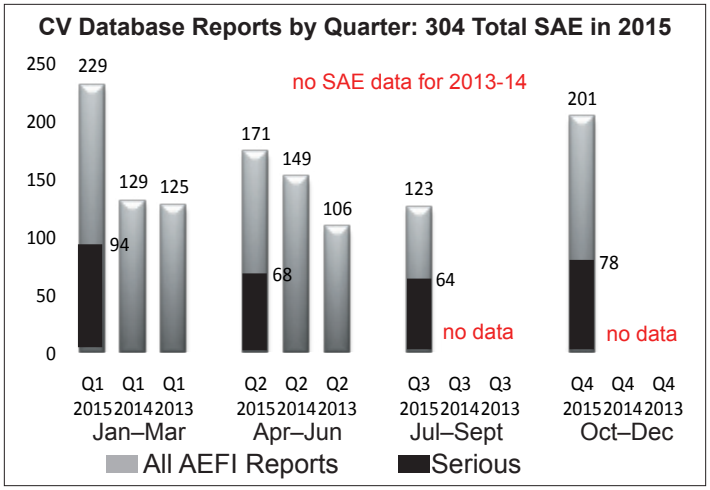
CAEFISS had 218 SAE reports and the CV database had 304.

- 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.

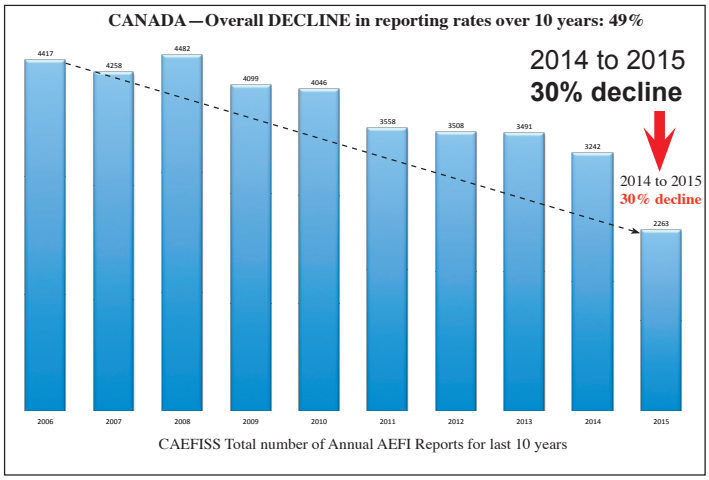
CV Database reports lack comparative data

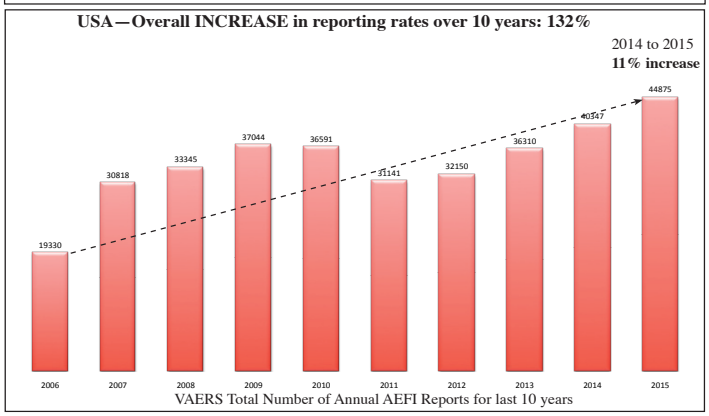
The graphic below shows the available CV data. The Q3 and Q4 reports did not include historical data as Q1 and Q2 reports did. No historical data on SAEs was included in any report. Therefore no trends can be tracked. Finally, there was no annual data in Q4 report.



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

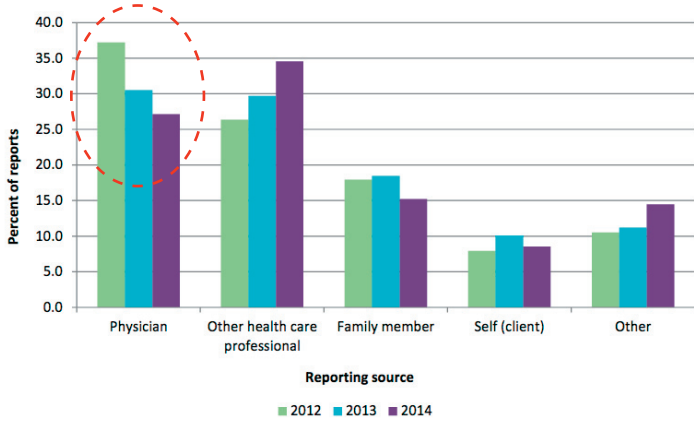


Table 2 from the Ontario report emphasizes the importance of doctor reporting. From the data given it appears Ontario doctors administer approximately 2 million

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

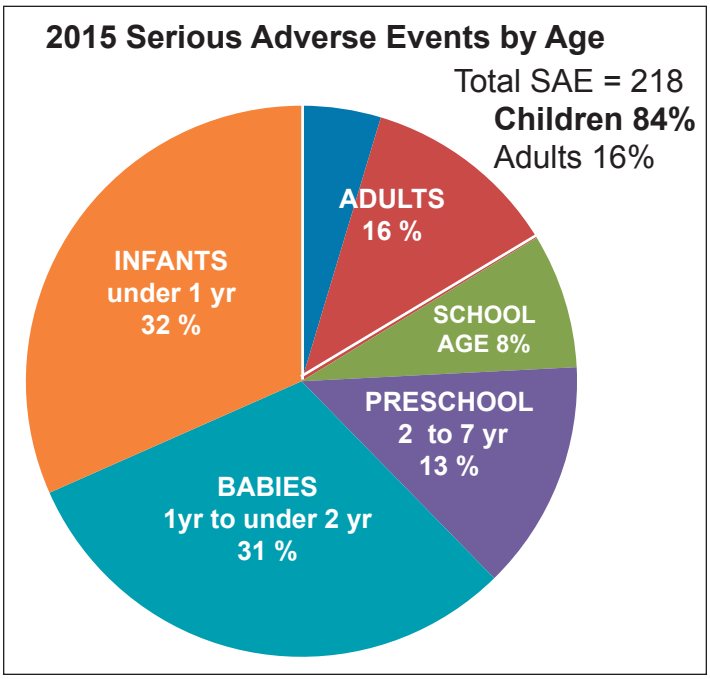
[2] AEFI Reports for Children less than 4 years of age following **Primary Care Administered vaccines** for DTap-IPV-Hib, Pneumonia C-13, Rotavirus, Meningitis C and MMR+V

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.

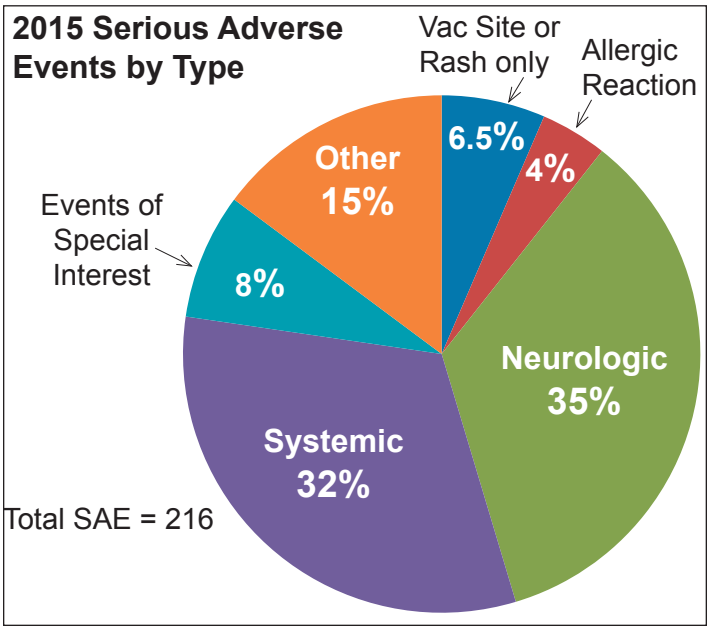


Children Experienced 84% of these Serious Events

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.