

• *Dedicated to all the vaccine injured, but especially the children* •

# Vaccine Safety Report 2

## An analysis of 2015 Adverse Events Data & Databases

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Underlined text in the pdf version of this report is hyperlinked to references.  
The hyperlinked pdf is available on our website's main menu at **About Vaccines/General Issues/Reports**.

### Preface

Canada's two Adverse Events surveillance systems are set up to analyze three things:

#### 1) **AEFIs**: Adverse Events Following Immunization

An AEFI is defined as “any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.”

#### 2) **SAEs**: Serious Adverse Events within all the AEFI reports.

An SAE is defined as one that results in

- Death or a
- Life Threatening event (say, cardiac arrest or anaphylactic shock)
- Hospitalization, or Extended Hospitalization if already hospitalized or
- Disability (say, paralysis or blindness) or
- Congenital deformity (relates to pregnant mother vaccination resulting in damage to the fetus)

#### 3) **Safety Signals**

Safety signals relate to the use of a vaccine in the general population after the vaccine has received license approval based on trials by the manufacturer of the vaccine. Their **pre-market** testing determines the list of adverse events in the product literature.

Safety signals are defined as follows:

- An increase in the severity or volume of known pre-market adverse events as documented in the product literature, or
- A post-market “incidence of interest” not documented in the product literature.

None of the recent (2014–2015) Quarterly reports for either the Canada Vigilance (CV) database or the Canadian Adverse Events Surveillance System (CAEFISS) have reported a safety signal. This despite the fact that at least one Safety Review of a vaccine was instigated in 2015 due to high volume of AEFIs.

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# 2015 Results in a Nutshell

## Vaccine-related Data & Reports are being OBSCURED

- Data in quarterly reports for both databases is being deleted or amalgamated reducing its usefulness.
- The Q4 2015 CAEFISS report is not found on internet searches.
- On the new website, historical Vaccine Safety Reports are no longer referenced. Only CAEFISS Quarterly Reports are found there.
- Vaccine Coverage of Canadian Children 2013 has been removed from the internet

### 2015 Total SAE from both Canadian Databases: 522

The combined total of Serious Reports from both databases is **522 serious reports** for 2015. CAEFISS had 218 SAEs and the CV database had 304.

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

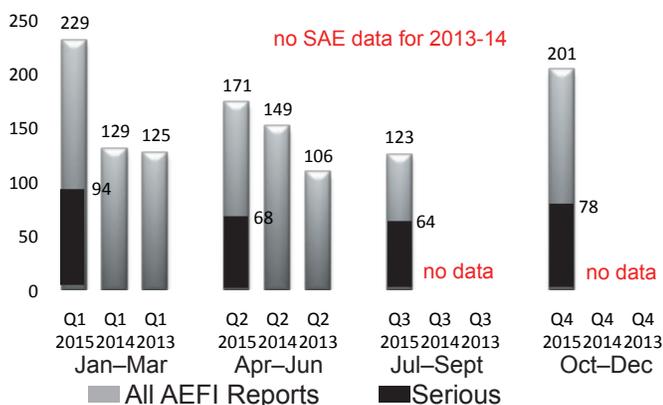
At a 10% reporting rate this means 5,220 Canadians experienced SERIOUS adverse events. (See reporting rate table in Introduction on page 4)

CAEFISS information and interpretations are therefore 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 on the serious events listed. We repeat our call for the two databases to be combined, to be publicly accessible and to have Annual Reports issued in a standard format for interpretation.

### CV Database reports lack comparative data

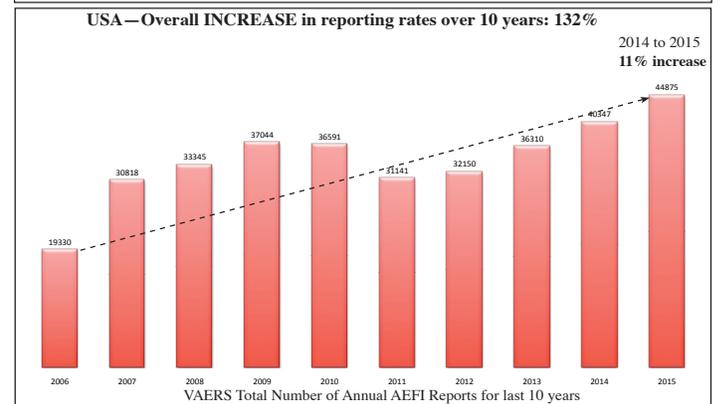
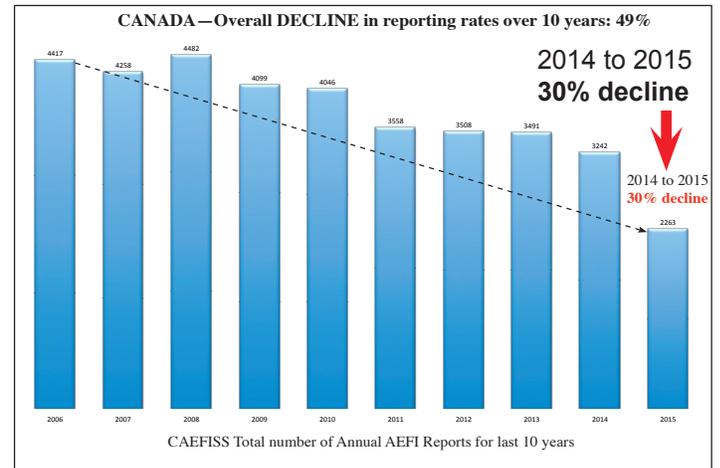
The graphic below shows the available data. The Q3 and Q4 reports did not include historical data as Q1 and Q2 reports did. No data on SAEs was included for the two previous years in any report. Therefore no trends can be tracked. Finally, there was no annual data in Q4 report.

### CV Database Reports by Quarter: 304 Total SAE in 2015



## Canadian Adverse Event Reporting Rates Continue to Decline

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



CAEFISS Quarterly reports do not give reporting source data. However the 2014 *Ontario Vaccine Safety Report* shows doctors were reporting fewer adverse events in 2012–2014: a 10% drop in fact.

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

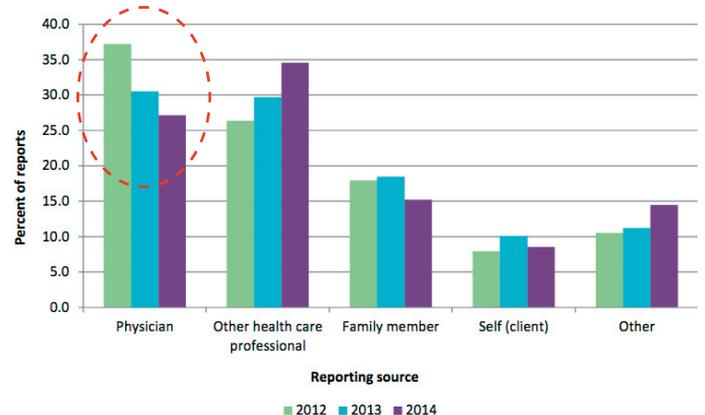


Table 2 from the Ontario report emphasizes the importance of doctor reporting. From the data given it appears Ontario doctors administer approximately

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 <sup>2</sup> distributed)	Count	Reporting rate (per 100,000 doses <sup>2</sup> distributed)	Count	Reporting rate (per 100,000 doses <sup>2</sup> distributed)
School-administered vaccines <sup>1</sup>	89	15.1	115	20.3	103	19.5
Primary care-administered vaccines <sup>2</sup>	110	5.6	122	6.0	101	4.9

**Notes:**

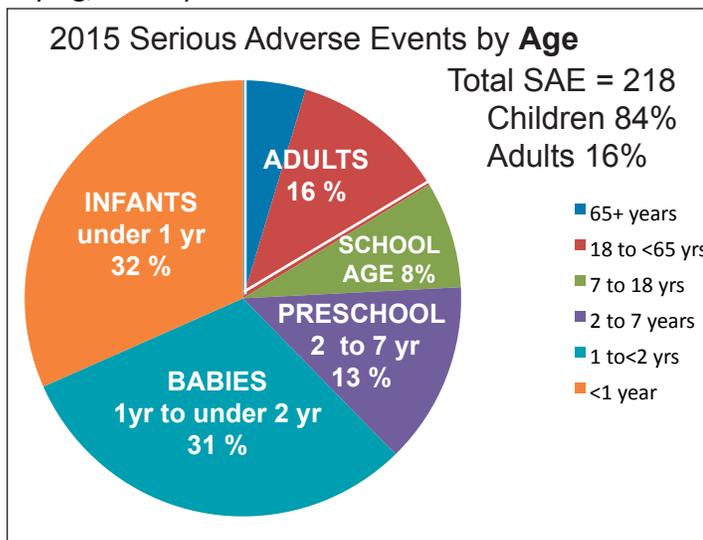
1. Includes AEFI reports occurring after the administration of Men-C-ACWY, HB, or HPV4 vaccines, in adolescents between 11 and 17 years of age, inclusive. See [Appendix 1](#) for a list of all possible vaccines, corresponding vaccine products and agent abbreviations.
2. Includes AEFI reports occurring after the administration of DTaP-IPV-Hib, Pneu-C-13, Rot-1, Men-C-C, MMR, or Var vaccines, in children less than 4 years of age.
3. Doses distributed are obtained from Ontario Government Pharmacy and Medical Supply Service (OGPMSS) and are calculated for school- and primary care-administered agents.

### 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.

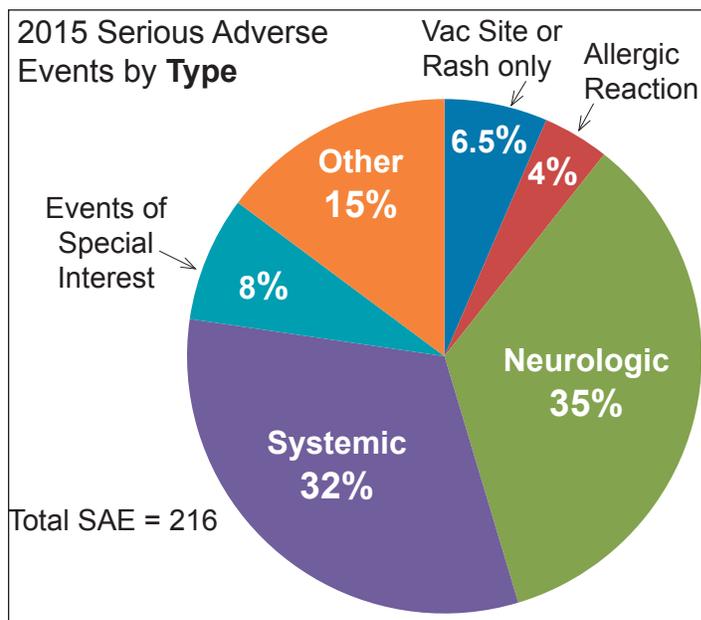


### Children Experienced 84% of these Serious Events

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** (see Preface on page 1). 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 reports never attribute deaths to suspect vaccines.

## Introduction

The Vaccine Choice Canada investigations into Canada's dual adverse events following immunizations (AEFI) databases began in the winter of 2015. The two separate databases are the Canada Vigilance (CV) database and the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). The [CV database](#) is posted on-line and is touted as searchable by the public. The [CAEFISS](#) data is accessible for public scrutiny only through reports released by the Public Health Agency of Canada (PHAC).

The [first VCC database report](#) was published in March 2015. An [update report](#) was published in July of 2015 as new data became available. The third report titled the [Vaccine Safety Report](#), was published in March of 2016 following the receipt of the full CV data for Q1 2015 from MedEffects™ Canada. This is the fourth report titled, *Vaccine Safety Report 2*.

Briefly we have learned the following from our investigations. See the reports above for details.

### Adverse Events Reporting

Only 1-10% of adverse events are actually reported. The databases contain only the reported events. This means that the number of **actual** adverse events that are occurring are much greater than the database numbers.

We found one instance of PHAC giving recent, concrete numbers of events per vaccine doses distributed in Canada for 2011 and 2012. (See page 9 of the first [Vaccine Safety Report](#) for details and links.) From that information we developed this reference table. AEFI are all adverse event reports. SAE refer to Serious Reports that have led to life threatening events, hospitalizations, prolonged hospitalizations, congenital defects, disabilities or death.

per 100,000 doses of vaccines distributed		
	AEFI	SAE
Number of Reported Events	15.2	.85
Number of Actual Events		
@ 10% reporting rate	152	8.5
Number of Actual Events		
@ 1% reporting rate	1520	85

From this table it is apparent that the oft-quoted number of adverse events as "1 in 1 million" is completely inaccurate. In the years 2011/12 the rate of actual adverse events for all vaccines was somewhere between 152 per 100,000 and 1,520 per 100,000 vaccine doses distributed. Serious events were somewhere between 8.5 per 100,000 and 85 per

100,000 vaccine doses. Generally then, since vaccine-related adverse events data reflects only reported events, **actual events are 10 times to 100 times more than the reported numbers**. This variance completely depends on the reporting rate.

### Three Systems Compared

**VAERS** is the American Vaccine Adverse Events Reporting System. It is functional and contains useful information.

- 1) It is easily searchable using a [search engine](#) developed by the National Vaccine Information Centre.
- 2) The data it contains on each event is voluminous compared to the scant data collected in Canada.
- 3) The number of VAERS reports has steadily increased over time with both population growth and an increasing number of vaccines on the market and added to childhood vaccine schedules.
- 4) The VAERS reporting rate of adverse events is unknown, but is variously reported as between 1% and 10% of ACTUAL Adverse Events Following Immunization.
- 5) The VAERS database is up to date. In October of 2016 it contains reports through July of 2016. That's a 3-month lag for data to be posted.
- 6) We highly recommend that Canadian citizen's use the VAERS search engine to understand adverse events related to specific vaccines or to all vaccines.

**CV** is the Canadian Vigilance database. It is not functional for public use.

- 1) This database is not searchable by the public in a manner that shows vaccine adverse events either for a single type of vaccine (e.g., All Influenza vaccines or all DTaP vaccines) or all types of vaccines (i.e., quarterly or annual counts of all vaccine-related adverse event reports).
- 2) It contains an increasing number of AEFI reports submitted in Canada, in 2015 more than half the reports.
- 3) But with little information on each event to the extent that the age and gender of the patient is often not recorded.
- 4) Scant data is reported in the Vaccine Safety Reviews instigated in 2015 on a quarterly basis by Health Canada in their newly titled [Health Products Infowatch](#) publication.
- 5) It is impossible to assess increase or decrease in reporting rates as the comparison data on

the number of AEFI/SAE reports from the last two years (2013 & 2014) is missing from last two quarterly reports.

6) No historical SAE data is given in the Safety Reviews.

6) The CV database is currently up to date only until March of 2016. That's a 5-month lag.

7) The Q4 2015 (Oct–Dec) CV *Safety Review* was published in August of 2016. That's an 8-month time lag to release 4 paragraphs of data.

**CAEFISS** has only limited functionality for public understanding of vaccine-related adverse events.

1) Adverse event reports are not available for public scrutiny

2) Data is released selectively (e.g., deaths are rarely reported) and brand names are not included.

3) The shift from sporadic (though lengthy and information-packed) annual reports to quarterly reports in 2014 has further restricted data available for public scrutiny.

4) The reporting rate has steadily decreased in Canada despite an increasing population and more

vaccines in the childhood vaccine schedule and available in the marketplace.

5) The latest quarterly report for Q4 2015 is not searchable on the Internet as all the others have been. It does not show up at all on search engines and is buried on the Healthy Canadians website behind four levels of page screens. VCC had to send an email request to CAEFISS for the location link in order to find the latest report.

6) No annual data is contained in Q4 2015 review, unlike the Q4 2014 report that did contain annual data. In any other sphere, the report for the last quarter of the year **always** includes annual data.

7) Data previously available is obscured by various means including combining categories, not giving percentages and using the less than symbol (<) rather than giving actual numbers in tables.

8) The Q4 2015 (Oct–Dec) CAEFISS report was posted on-line on Sept 30, 2016. That's a 9-month time lag.

**Canadians deserve far more timely, accessible, accurate and comprehensible data on vaccine-related adverse event reports.**

## Part 1: Canada Vigilance On-Line Database

### AEFI Reports 2015

Because the CV database is not searchable for aggregate numbers of vaccine-related adverse event reports, the public must rely on the Vaccine Safety Reviews issued quarterly by MedEffect™ Canada.

The reviews only began in the first quarter (Q1) of 2015. The chart below reflects the scant data published to date. No comparison data to previous years was supplied for Q3 and Q4. Thus scant data became scantier. MedEffect™ Canada has not responded to our

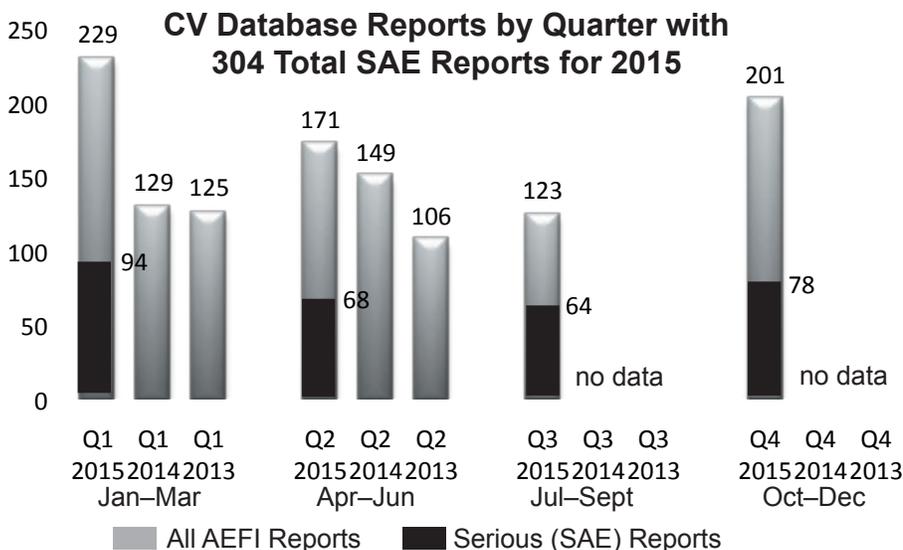
request for the 2013-14 comparison data. Looking at the first two quarters, it is obvious that an increasing number of reports are being recorded for the 3 years shown. However whether this is a trend remains to be seen when more data becomes available.

Manufacturers and distributors of vaccines are required by law to report Serious Adverse Events (SAE) to the Canada Vigilance program. Regardless of the legal requirement, it is a self-monitored reporting program. As you see in the text from the Vaccine Safety

Reviews on the next page, voluntary AEFI reports are also received and recorded.

The number of reported **Serious Adverse Event total 304** based on the 4 quarters of 2015: Q1 94 SAE, Q2 68 SAE, Q3 64 SAE, Q4 78 SAE. Serious reports are not necessarily submitted only by manufacturers (MAH). Many of the voluntary SAE reports are submitted by health care professionals and the public.

When we inquired if CV AEFI reports were duplicates of the ones on CAEFISS, we were assured by MedEffect™ that they were not.



Below are the Q3 and Q4 Vaccine Safety Reports. The introductory paragraphs are the same for each report as follows:

“Post-market surveillance is essential to monitor the safety and effectiveness of vaccines and other health products. The monitoring of the safety of vaccines is a shared responsibility between Health Canada and the Public Health Agency of Canada (PHAC).

Market authorization holders are required to report serious adverse events following immunization (AEFIs) to the Canada Vigilance Program in the Marketed Health Products Directorate at Health Canada. The Canada Vigilance Program also receives voluntary AEFI reports from healthcare professionals and consumers. Provincial and territorial public health authorities report AEFIs from publicly funded vaccine programs to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) in PHAC to monitor the safety of immunization programs.

This Vaccine Safety Review summarizes AEFI reports received by the Canada Vigilance Program between October 1, 2015 and December 31, 2015. To access reports published by CAEFISS, please visit the CAEFISS website.”

### Vaccine Safety Review [Q3]

#### Report for July 1, 2015 to September 30, 2015

- From July 1, 2015 to September 30, 2015, the Canada Vigilance Program received 123 reports of adverse events for which vaccines were the suspected cause.
- As in the previous quarters of 2015, the majority of the reports received involved Bexsero (multicomponent meningococcal B vaccine [recombinant, adsorbed]; 37 reports) and Zostavax (zoster vaccine live, attenuated [Oka/Merck]; 25 reports).
- There were 64 (52%) serious reports. Most of these involved patients with underlying medical conditions and were unlikely related to the vaccination.
- The most frequently reported AEFIs were diarrhea, nausea, pain in the extremities, headache, malaise, myalgia, pyrexia, vaccination site erythema and fatigue. The majority of these adverse events involved Bexsero and Zostavax. These are known events following immunization and are included in the respective Canadian product monographs.
- No new safety signals (potential safety issues) were identified during this period.
- The benefits of vaccines authorized in Canada continue to outweigh the risks.
- Health Canada, in collaboration with PHAC, will

continue to closely monitor the safety of vaccines authorized in Canada.

### Vaccine Safety Quarterly Summary [Q4]

#### Report for October 1, 2015 to December 31, 2015

- From October 1, 2015 to December 31, 2015, the Canada Vigilance Program received 201 reports of adverse events for which vaccines were the suspected cause.
- The largest proportion of the reports received (50 %) were for influenza vaccines, which is expected during the “Influenza Immunization Awareness Campaign in Canada”.
- There were 78 (39%) serious reports. Most of these involved patients with underlying medical conditions and were unlikely related to the vaccination.
- The most frequently reported AEFIs were injection site erythema, pyrexia, urticaria, and headache. The majority of these adverse events involved influenza vaccines. These are known events following immunization and are included in the respective Canadian product monographs.
- No new safety signals (potential safety issues) were identified during this period.
- The benefits of vaccines authorized in Canada continue to outweigh the risks.
- Health Canada, in collaboration with PHAC, will continue to closely monitor the safety of vaccines authorized in Canada.

### Bexsero and Zostavax Vaccines

The first VCC *Vaccine Safety Report* contained in-depth discussions regarding both Bexsero (MenB) and Zostavax (shingles) vaccines as they were mentioned in the Vaccine Safety Reviews for Q1 and Q2 2015. The Q3 Safety Review also mentions these two vaccines:

“As in the previous quarters of 2015, **the majority of reports received** involved Bexsero (multicomponent meningococcal B vaccine [recombinant, adsorbed]; 37 reports) and Zostavax (zoster vaccine live, attenuated [Oka/Merck]; 25 reports).”

Since the number of Serious reports for each vaccine is not given for Q3, the database was searched for this information.

Q3 2015 Totals:	AEFI 123 reports	SAE 64 reports
Bexsero	AEFI 37—30%	SAE 12—19%
Zostavax	AEFI 25—20%	SAE 15—23%

- These 2 vaccines account for 50% of all AEFI reports and 42% of all Serious reports in Q3.

These two vaccines are not mentioned at all in the Q4 *Safety Review*, so the CV database was searched for

this information with the following results:

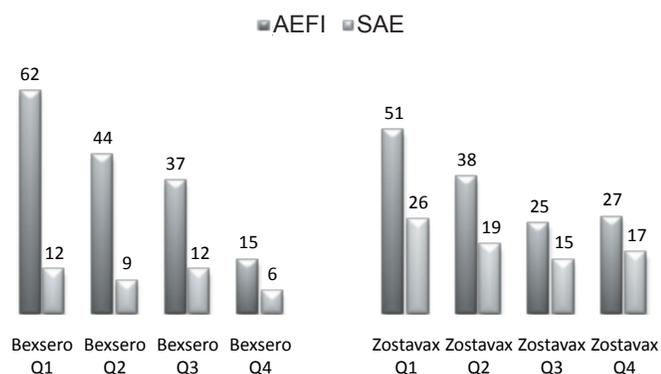
Q4 2015 Totals: AEFI 201 reports SAE 78 reports  
 Bexsero AEFI 15–8% SAE 6–8%  
 Zostavax AEFI 27–13% SAE 17–22%

- These 2 vaccines account for 21% of all AEFI reports and 30% of all Serious reports in Q4.

As the Q4 report notes, 50% of all reports were for influenza vaccines: 100 reports. No mention is made of the number of serious reports for influenza vaccines. For reasons discussed in the *First VCC Vaccine Safety Report*, the database cannot be easily searched for flu vaccines. Influenza vaccines will be discussed in more depth later in this report.

Below is a 2015 annual chart for AEFI reports for Bexsero and Zostavax. The reports are declining in

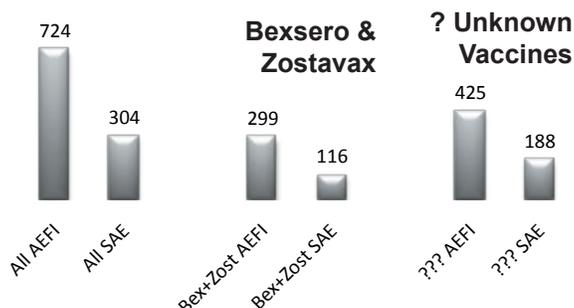
### 2015 Number of AEFI & SAE Bexsero & Zostavax Vaccines



number. Although Zostavax Serious Report numbers are fairly stable in the last 3 quarters.

Totaling reports in all quarters for these 2 vaccines and comparing them to the total number of reports for 2015, results in the chart below. This chart shows that only about 40% of AEFIs/SAEs were discussed in the *Vaccine Safety Reviews*. The public has little idea of the safety profiles of other vaccines as no data is given (except in Q4 2015 when 100 AEFI reports for influenza vaccines were noted).

### 2015 Total AEFI & SAE Reports



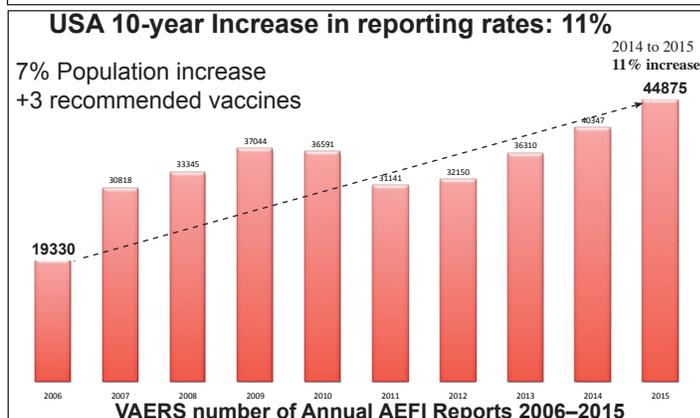
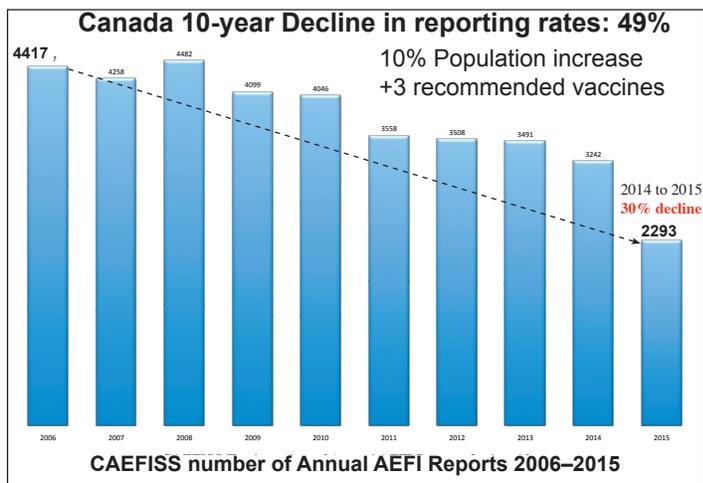
## Part 2: CAEFISS Database

### AEFI Reports 2015

The CAEFISS Quarterly Reports are not only presenting less data than they did in the recent past (just like the Canada Vigilance quarterly Safety Reviews); but in the fourth quarter the CAEFISS Report could not be found by searching on-line. As explained in the introduction, it was only by emailing CAEFISS that the link to the Report was found on the Healthy Living website. When we began this report the website said: “We are in the process of moving our publications to Canada.ca.” This is now completed and adds one more layer of page screens to go through to find the publications on [Immunizations & Vaccines](#). There are no links to any of the pre-2014 PHAC or Health Canada publications on this subject at this location. The three previous VCC adverse event reports have links to these older publications or they can be found on the [CAEFISS](#) site.

### Is There a Chill on AEFI Reporting in Canada?

Returning to a major theme of the first *Vaccine Safety Report*, the number of AEFI reports on CAEFISS was down by 30% in 2015. No other year in the last ten has shown such a decline in reported events. Meanwhile, in the US with an almost identical vaccine schedule, AEFI reports continue to increase, up 11% in 2015.



There is no way to explain away this disparity in reporting rates between the USA and Canada.

### Canada & USA Population Growth

Canada’s population increased by 10% from 2006 to 2015 (from 32.7 million to 36 million). The US population increased by 7% in the same 10 year period (from 298.4 million to 320.2 million). Population growth in both countries means more vaccine uptake over this period.

### Canada & USA Vaccine Availability and Use

“Active vaccines” are vaccines available for use. According the 7th Edition of the Health Canada Immunization Guide, in 2006 there were 21 active vaccines available in Canada. By 2015 the Immunization Guide shows three more vaccines—HPV, Rotavirus and Herpes Zoster—had been added to the list for a total of 24 active vaccines. In 2015, the USA listed these same 24 vaccines types (plus 3 more which are licensed but not in common use—anthrax, plague and adenovirus). The Table below lists the 24 active vaccines used in both countries and notes childhood use in each country as well.

Since the number and kinds of vaccines used in the USA and Canada are the same, this cannot account for the declining reporting rates in Canada and the increasing rates in the USA.

It is also useful to compare the recommended childhood vaccine schedules for Canada and the USA as this accounts for the largest portion of vaccine use; and also the largest proportion of AEFI reports.

In 2006 in Canada there were 13 vaccines used in the childhood vaccine schedule. In 2006 in the USA there were 14 vaccines being used. The difference is the USA gave (and still gives) HepA vaccine to babies. Canada has never recommended this use. By 2015, there were 15 vaccines in the childhood schedule in Canada since HPV and Rotavirus had been added. For the same reason there were 16 vaccines given in the US in that year.

Dosages were the same, except as follows:

In 2006

- 1) IPV (polio): Canada—5 doses, USA—4
- 2) Hib: Canada—3 or 4 doses, USA—3 doses
- 3) MenC: Canada—2 or 3 doses to babies, USA —2 doses at 12 and 16 years of age
- 4) HepA: USA—2-doses beginning at 1 year of age, Canada— none

In 2015

- 1) IPV (polio): Canada—5 doses, USA—4
- 2) Hib: Canada—3 or 4 doses, USA—3 doses
- 3) MenC: Canada—1 dose at 6 months, 2nd dose at 12 years, USA —2 doses at 12 and 16 years of age
- 4) HepA: USA—2-doses beginning at 1 year of age, Canada— none

Overall, Canadian and American children are receiving the same vaccines (except HepA) at almost the same dosages. Both countries have increased the number and dosages of vaccines in the childhood vaccine schedule over the 10 year period from 2006 to 2015.

**The VAERS reporting system reflects these changes. The CAEFISS system emphatically does not.**

Is it the increased pressure from public health officials and professional associations on doctors, nurses and pharmacists to vaccinate children and the elderly to “protect the herd” that lies somewhere at the bottom of Canada’s significantly declining reporting rates? After all, it is those administering vaccines who are also responsible for reporting adverse events.

Vaccines are not getting “safer”, thus this cannot account for fewer reports. In fact, the newer vaccines are even more reactogenic (and more expensive) than the older vaccines. At bottom, it is our children who bear the brunt of Serious Adverse Events. Both of these topics are explored in the following sections.

### Dumbed Down Reports

One final comment on the CAEFISS Reports is necessary. Both the quality and quantity of information in the reports is seriously deteriorating. It is more difficult to realistically compare data to past reports which are themselves disappearing. Categories are being eliminated or amalgamated obscuring data. Even

Active Vaccines Canada & USA	Pediatric Use	
	Canada	USA
Bacille Calmette-Guérin Vaccine (TB)		
Cholera (a travellers vaccine)		
Diphtheria Toxoid (the D in DTaP and Tdap)	X	X
Haemophilus Influenzae Type B Vaccine (Hib)	X	X
Hepatitis A Vaccine	NO	X
Hepatitis B Vaccine	X	X
Herpes Zoster (Shingles) Vaccine (shingles)		
Human Papillomavirus Vaccine (HPV)	X	X
Influenza Vaccine	X	X
Japanese Encephalitis Vaccine (a travellers vaccine)		
Measles Vaccine (the first M in MMR and MMRV)	X	X
Meningococcal Vaccine	X	X
Mumps Vaccine (the second M in MMR)	X	X
Pertussis Vaccine (the aP in DTaP and Tdap)	X	X
Pneumococcal Vaccine (pneumonia)	X	X
Poliomyelitis Vaccine (IPV for polio)	X	X
Rabies Vaccine		
Rotavirus Vaccine	X	X
Rubella Vaccine (the R in MMR and MMRV)	X	X
Smallpox Vaccine		
Tetanus Toxoid (the T in DTaP and TDaP)	X	X
Typhoid Vaccine (a travellers vaccine)		
Varicella (Chickenpox) Vaccine (the V in MMRV)	X	X
Yellow Fever Vaccine (a travellers vaccine)		

the actual numbers of AEFI reports in some tables are now being listed as <5, so percentages are difficult to calculate.

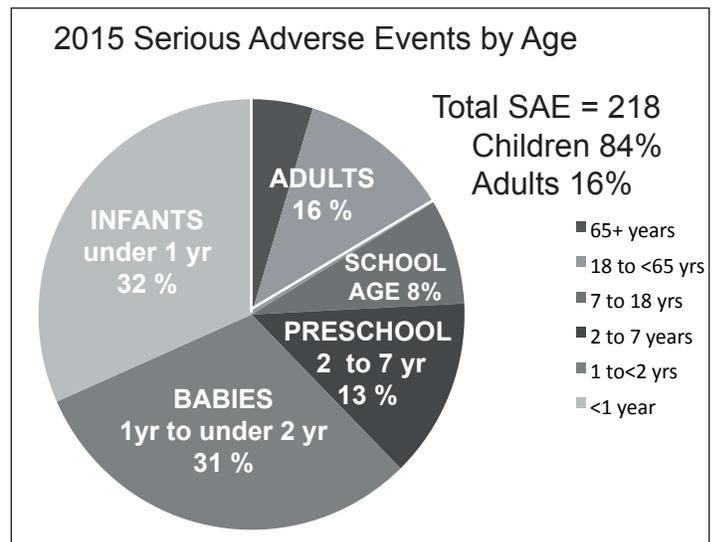
### Children and Serious Adverse Events

In the 2015 Adverse Events Update Report, we presented a table showing the number and percent of all Serious Adverse Events reported for children. Below is that table updated with the 2015 data. Updating this table was arduous. The CAEFISS Q4 2015 Quarterly Report did not contain any annual data. It presented a chart with the number of serious and non-serious reports for each quarter in 2015; but the SAE numbers given for Q1 and Q2 were different than the original reports. Everything had to be recalculated from each original 2015 quarterly report.

Since 2013 data has never been available except as average numbers in 2014 quarterly reports, we cannot verify the accuracy of the averages. For this reason, the actual 2014 numbers remain in our chart. This way we can compare year on year data as we move forward.

One other complication arose. The table in Q4 that shows SAEs stratified by age group suddenly has “<5” instead of an actual number (1, 2, 3, or 4) for SAE reports. Why not just type in the number? We used our best judgement and/or extrapolation to insert actual numbers in the table. Since percentages were also not included as in past years, we calculated those. And as a final move, the age order was flipped upside down in Q4 2015 from all previous years. We see no logical reason why these changes were made except to make previous years comparisons more difficult.

In the table below and the pie chart above, it is immediately obvious that children are suffering over



80% of serious, often life threatening and certainly life-changing, adverse events. Babies under 2 years of age are suffering more than 60% of all these serious adverse events.

And we must remind you, these are only reported events. If in fact the rate of serious adverse events reporting is 10% of actual events, then that means 1,800 children (10X180) including 1,340 babies (134X10) were **seriously** affected by vaccines in 2015.

We have been vaccinating babies with an increasing load of vaccines for over 50 years. That adds up to a lot of damaged babies and children.

Another way of understanding the extent of adverse events was shown before the change to quarterly reports in the last competent and comprehensive adverse events report from PHAC issued in December of 2014. That is, reporting based on population was presented. The table from that report is reproduced on the next page. It shows (for the 8-year span in the

Cumulative serious and non-serious AEFI reports for 2015 Stratified by age group and Compared to 2014 and to the average for 2011-2013.						
Age Group	Serious Adverse Events (SAE)			Non-serious Adverse Events (non-SAE)		
	2015	2014	Avg. for 2011-13	2015	2014	Avg. for 2011-13
	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
Unknown	0	3 (1.3)	2 (0.9)	14	23 (1.1)	81 (2.5)
65+ years	10 (4.7)	11 (4.91)	18 (8.2)	261	229 (10.5)	279 (8.5)
18-<65 years	25 (11.6)	31 (13.8)	26 (11.8)	798	780 (35.7)	1008 (30.6)
7-<18 years	17 (7.9)	16 (7.1)	20 (9.1)	358	388 (17.8)	446 (13.5)
2-<7 years	29 (13.5)	26 (11.6)	25 (11.4)	180	270 (10.5)	445 (13.5)
1-<2 years	66 (30.7)	59 (26.1)	69 (31.4)	250	230 (10.5)	579 (17.6)
0-<1 year	68 (31.6)	78 (34.8)	61 (27.7)	221	264 (12.1)	460 (13.9)
Subtotals:						
<b>Children</b> 0 to 18 yr	180 (83.7%)	179 (79.6)	175 (79.6)			
<b>Babies</b> 0 to 2 yr	134 (62.3%)	137 (60.9)	130 (59.1)			
<b>Total</b>	218	224	221	1882	2184	3298

**Table 3: Annual age-specific AEFI<sup>1</sup> and SAE<sup>2</sup> reporting rates per 100,000 population for vaccines administered from 2005 through 2012**

Age group	AEFI (SAE) reporting rates per 100,000 population							
	2005	2006	2007	2008	2009	2010	2011	2012
<1 year	176(16)	161(16)	169(18)	134(12)	152(19)	150(20)	136(15)	130(12)
1 to <2 years	305(22)	290(24)	276(22)	283(22)	238(18)	217(18)	202(17)	152(16)
2 to <7 years	47.1(1.2)	36.7(1.1)	31.5(1.2)	31.0(1.2)	27.8(1.0)	28.7(1.0)	28.8(1.4)	25.2(1.2)
7 to <18 years	11.9(0.5)	11.4(0.4)	9.5(0.4)	15.1(0.6)	12.3(0.5)	12.0(0.4)	9.7(0.6)	11.2(0.4)
18 to <65 years	6.5(0.2)	6.0(0.1)	6.0(0.1)	5.6(0.1)	4.9(0.2)	4.7(0.1)	4.2(0.1)	5.0(0.1)
65+ years	8.0(0.3)	6.6(0.2)	6.3(0.2)	6.8(0.2)	4.3(0.3)	7.1(0.5)	5.3(0.3)	5.8(0.3)
All ages	14.8(0.7)	13.5(0.6)	12.9(0.7)	13.4(0.6)	12.1(0.7)	11.9(0.7)	10.3(0.6)	10.1(0.6)

table) that for babies under 1 year of age an **average** of 18 per 100,000 vaccinated experienced a reported Serious Adverse Event. For babies from 1 to <2 years age an **average** of 20/100,000 babies vaccinated were affected.

In 2010 and 2011, Statistics Canada reports there were 377,213 and 377,636 live births, respectively. Every two years PHAC releases data on a National Immunization Coverage Survey. The 2015 report (covering 2013 data for children up to 2 years of age) has been inexplicably removed from the internet; however we captured the data in our July 2015 Adverse Events Update report. See that table below.

With the live birth and coverage data we can calculate the number of 1-year old and 2-year old babies vaccinated in 2011 for DTap-IPV-Hib and MMR vaccines and using the reporting rates per 100,000 estimate the expected number of SAEs.

Results for 2011 are as follows.

- 3 doses of DTaP-IPV-Hib by 1 year of age:  
At 88% coverage of 377,636 babies born = 332,320 babies vaccinated.  
At 15 SAEs/100,000, we would expect to see **50 SAEs** reported for this cohort in 2011.

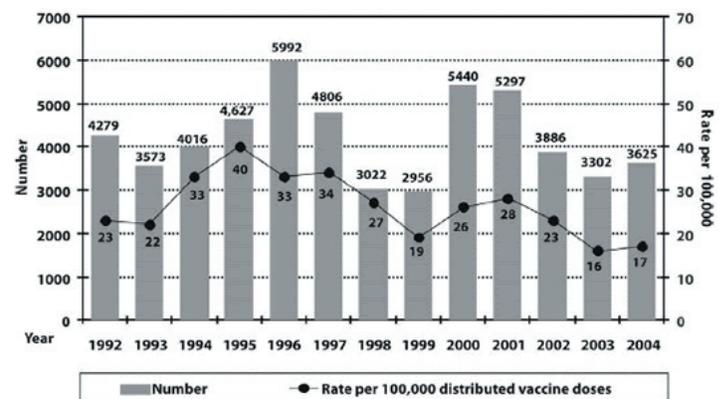
- 2 doses of MMR by 2 years of age:  
At 95% of 377,213 = 358,352 babies vaccinated.  
At 17 SAEs/100,000, we would expect to see **61 SAEs** reported for this cohort in 2011.

Of course these estimates are lower than the total events reported in the Cumulative Table on the previous page which includes SAEs for all vaccines for these age groups. But they bring into focus the actual number of babies affected by “per 100,000 population reporting rates” in a given year.

### Reporting AEFIs per Vaccine Doses

The text of the Canadian National Report on Immunization for 2006 states they are receiving between 4,000 and 5,000 AEFI reports annually. Then presents the following table. This was the only time that annual AEFI rates per net vaccine doses were reported. By the time the next Canadian Immunization report was released in 2014, the number of vaccine doses distributed had become **proprietary information** of the vaccine manufacturers. This policy decision should be reversed. Especially since we are seeing the more reactogenic new vaccines seriously affecting children.

**Figure 10. Number of AEFI reports and reporting rates per 100,000 doses of distributed\* vaccines, 1992 to 2004**



\*Net number of doses distributed (doses distributed minus doses returned)

Comparison Chart: 2011 & 2013 Immunization Coverage for 2 year old Children			
Disease	2011	2013	Difference
Diphtheria	87.9%	77.4%	-10.5%
Pertussis	87.9%	77%	-10.9%
Tetanus	87.9%	77%	-10.9%
Polio (IPV)	96.2%	91.1%	-5.1%
Hib	87.9%	72.7%	-15.2%
Measles	95.2%	89.6%	-5.6%
Mumps	95.2%	89.2%	-5%
Rubella	95.2%	89.2%	-6%
Varicella	88.6%	73.1%	-15.5%
Meningococcal C	80.5%	88.6%	+8%
Pneumococcal	76.5%	79.3%	+3.2%

## IMPACT

The IMPACT surveillance system in pediatric hospitals in Canada is an active (not passive) surveillance system and reports to CAEFISS. It is estimated this system captures 90% of children hospitalized for all causes in Canada. However Impact is not reporting 90% of SAEs. In fact looking at the charts in the [2014 CAEFISS Immunization Report](#), which covers the years 2005 through 2012, it appears that in 2005 the provincial and territorial (P/T) public health reports comprised 55% of total SAE reports and Impact reports accounted for 45%. In 2012, Impact accounted for 57% of SAE reports and P/T public health reported 43%. We have no data after 2012. (And no indication whether PHAC will continue to report annual data in comparative reports in the future.) We do note that Ontario (accounting for about 33% of Canada's population) reported in their [2014 Annual Report on Vaccine Safety](#) that IMPACT accounted for just 1/3 of SAE reports (8 out of 23) in that province.

A December 2014 *Canadian Communicable Disease Report* (CCDR) [article](#) shows what the surveillance targets of IMPACT actually are. Table 1 below helps to understand why their report numbers are low as it itemizes the serious reactions they are looking for and reporting on.

It is important to understand there are almost 8,000 terms for serious adverse reactions on the [Medra 1.9](#) list of such events for all drugs. Then it is interesting to see the adverse events related to vaccines targeted by another country.

Recently we requested the adverse reaction information for the UK Childhood Vaccine Schedule from MHRA, the Medicines and Healthcare products Regulatory Agency. We received hundreds of pages of reactions to the vaccines. Each vaccine had a list of disorder categories including but not limited to:

Blood, Cardiac, Congenital, Ear, Endocrine, Eye, Gastrointestinal, General (included Injection site), Hepatic, Immune System, Infections, Muscle & Tissue, Neoplasms, Nervous System, Pregnancy conditions, Psychiatric disorders, Renal & Urinary, Respiratory, and Vascular.

Most of these disorder categories then had scores of subcategories and then many different reactions under each sub-category. The number of reports for each event, totals for each category and fatalities were shown for each vaccine. Of course they were not all serious adverse reactions, but many were. And they were reactions in many, many more categories than shown in the IMPACT table below.

**Table 1: The Canadian Immunization Monitoring Program ACTIVE (IMPACT) adverse events following immunization surveillance targets and reporting intervals, 2014**

Specific targets	IMPACT intervals for reporting
<b>Neurologic Events</b>	
Seizure	0–3 days after inactivated vaccine(s); 0–15 days after live vaccine(s) <sup>1</sup>
Guillain-Barré syndrome (GBS)	0–42 days after inactivated or live vaccine(s)
Other acute flaccid paralysis (AFP)	0–42 days after inactivated or live vaccine(s)
Encephalitis	0–42 days after inactivated or live vaccine(s)
Acute disseminated encephalomyelitis (ADEM)	0–42 days after inactivated or live vaccine(s)
Myelitis	0–42 days after inactivated or live vaccine(s)
Aseptic meningitis	0–42 days after inactivated or live vaccine(s)
<b>Thrombocytopenia</b> (<100 x 10 <sup>9</sup> /litre with clinical evidence of bleeding, including Idiopathic Thrombocytopenic Purpura (ITP) <sup>2</sup>	0–42 days after inactivated or live vaccine(s)
<b>Intussusception</b> in infants <1 year of age	Within 0–21 days after live attenuated rotavirus vaccine only
<b>Vasculitides</b> (Kawasaki disease, Henoch-Schonlein Purpura (HSP), etc.)	0–42 days after inactivated or live vaccine(s)
<b>Complication of vaccination</b>	
Anaphylactic shock	48 hours after any vaccine
Vaccination site cellulitis or abscess	No specific timeline but needs to be localized to the vaccination site.
Non-vaccination site infectious complication including sepsis or infection of a normally sterile body site	No specific timeline but needs clear evidence linking the infection to a prior vaccination.
Varicella vaccine reactivation illness (Varicelliform rash or Zosteriform rash)	>42 days after varicella vaccination
<b>Other AEFIs:</b> All <i>reportable</i> AEFIs that the monitor finds during searches for the above IMPACT targets.	Follow the CAEFISS user guide

Source: CCDR Dec 4, 2014 • Volume 40 S•3 ISSN 1481–8531

## CAEFISS Over Time

A very interesting 2011 [slide show](#) by Barbara Law, Chief of Vaccine Safety at PHAC, details information from 1987 (the start date of CAEFISS) through 2011. Two of those slides are presented here.

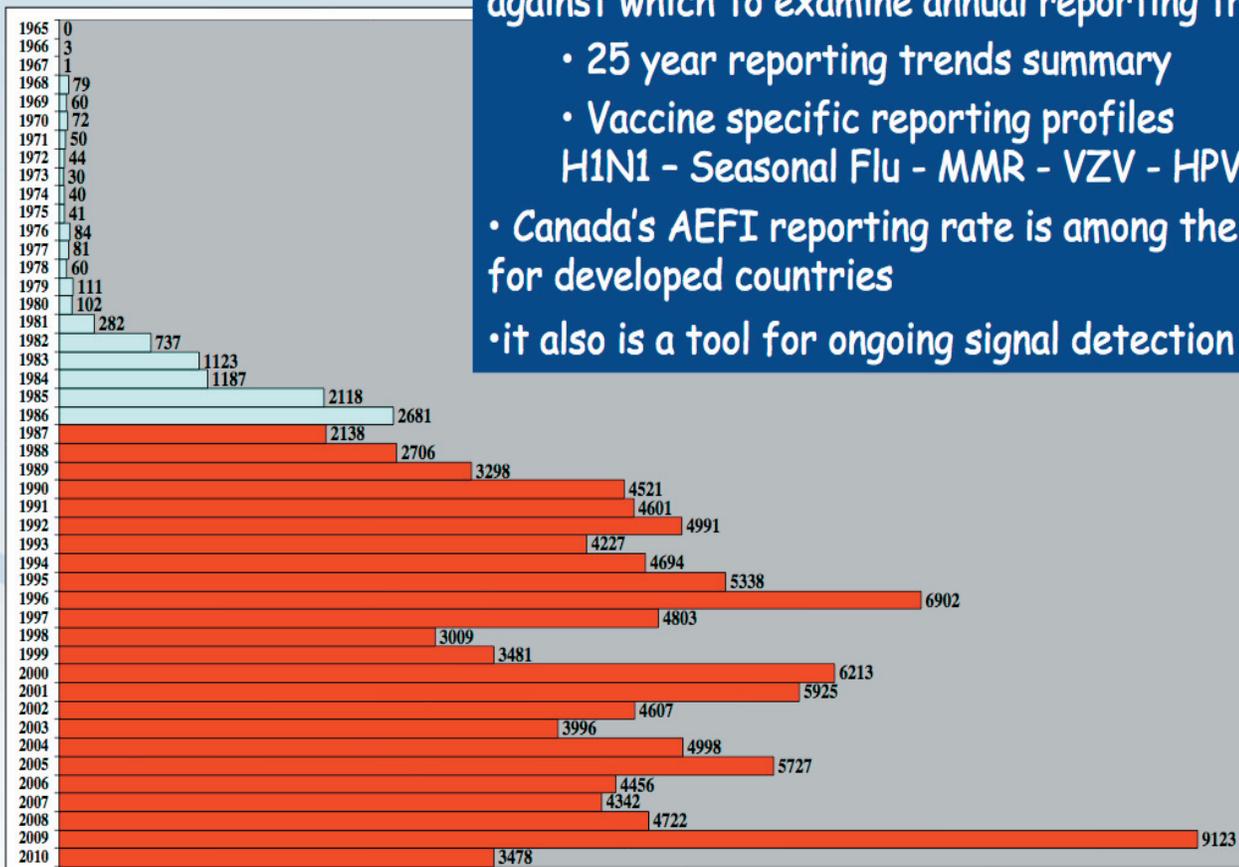
Slide 54 below is interesting for a couple of reasons. First, the reports from 1965 through to 1986 are the Canada Vigilance (CV) database reports. In 1987 when CAEFISS was created something very strange happened on the CV database. Namely, one can search those early years using the word vaccine(s). Our searches of the CV database detailed in the first VCC Adverse Events Report replicate the numbers in the slide below. After 1987 hardly any reports are returned when searching the CV database with the word vaccine(s). We surmise that when the CV database was the only source for vaccine Adverse Events data, a search function for vaccines was active. Once the CAEFISS database was established, this search function was apparently discontinued. Although the CV database is still touted

as being functional for public searches, it no longer is. Removing this search function shows a terrible disregard for the interests of the Canadian public and a very serious lack of accountability and transparency on the part of Health Canada's MedEffect™ Agency who administer this database.

Another interesting fact is this slide has not scrubbed the H1N1 pandemic flu vaccine reports from 2009. We have pointed out previously that the [2014 CAEFISS Annual Report](#), covering data from 2005 to 2012 stated [emphasis ours]:

“Of 38,364 extracted AEFI reports, **5,204 involving pandemic vaccine given alone were excluded** since this vaccine was used only in 2009–2010. Of the 33,160 reports for analysis, the distribution of AEFI (% SAE) reports by year vaccine administered was: 2005: 4,792 (4.5%); 2006: 4,417 (4.8%); 2007: 4,258 (5.3%); 2008: 4,482 (4.7%); 2009: 4,099 (5.8%); 2010: 4,046 (5.9%); 2011: 3,558 (5.8%); 2012: 3,508 (5.4%).”

## Canadian AEFI Reports 1965-2010



- CAEFI database now has >15,000,000 reports
- the database now represents a valuable resource against which to examine annual reporting trends
  - 25 year reporting trends summary
  - Vaccine specific reporting profiles  
H1N1 - Seasonal Flu - MMR - VZV - HPV - PneuC
- Canada's AEFI reporting rate is among the highest for developed countries
- it also is a tool for ongoing signal detection

In fact upon inspection we found the years 1992–2010 in Slide #54 show different AEFI numbers than those publicly reported by CAEFISS. Both the 2014 report cited above and the 2006 National Report on Immunization have different AEFI report numbers than the slide. Our calculations show a total difference of almost 14,000 AEFI reports for those 10 years. Discounting the 5,204 H1N1 AEFI reports, the difference is still 8,543 AEFI Reports. This begs the question of why these 8,500 reports were removed prior to public reporting. If Slide 54 is to be believed then this “valuable resource against which to examine annual reporting trends” is a more complete database than the one being reported on to the public. Again the question of public transparency and accountability is brought to the fore.

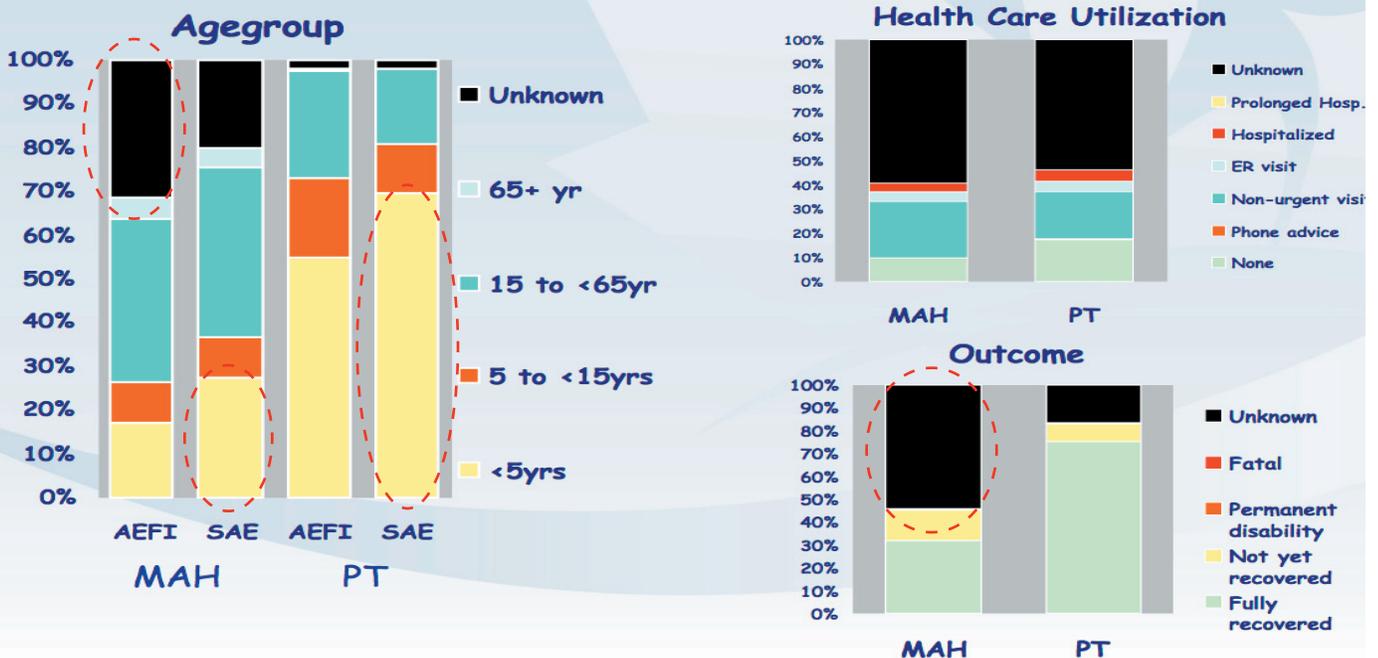
The other slide of particular interest is #55 below (to which we added the circles and arrow). This slide shines a light on the reporting habits of MAHs (manufacturers and distributors of vaccines). Note that MAH reports have over 30% of AEFI reports with no ages listed. Also note the proportion of their SAE reports for children under 5 years (yellow, >30%) does not match the preponderance of SAE reports from the P/T for this age group (yellow, 70%). In the Outcome chart more than 50% of the MAH reports have unknown outcomes. Ditto with the Health Care Utilization chart. This slide confirms our previous discussions of lack of information in MAH legally-required SAE reports. It is

Two CAEFISS Databases?			
Year	CAEFISS	Slide	Difference
1992:	4279	4991	-712
1993:	3573	4227	-624
1994:	4016	4694	-678
1995:	4627	5338	-711
1996:	5992	6902	-901
1997:	4806	4803	+3
1998:	3022	3009	+13
1999:	2956	3481	-525
2000:	5440	6213	-628
2001:	5297	5925	-773
2002:	3886	4607	-628
2003:	3302	3996	-721
2004:	3625	4998	-1373
2005:	4792	5727	-935
2006:	4417	4456	-39
2007:	4258	4342	-84
2008:	4482	4722	-240
2009:	4099	9123	-5024
2010:	4046	3478	-568
	<b>Difference</b>		<b>-13,747</b>
	<b>Less HINI</b>		<b>5,204</b>
			<b>-8,543</b>

also interesting to note that MAH reports account for only 6% of all reports to CAEFISS from 1997 to 2011. In 2011, MAH were to begin reporting exclusively to the CV database. Whether this has happened, we have no way of knowing.

## AEFI Report Profile by Onward Reporter: 1987–2011

115,837 reports in total; 6180 (5.3%) Serious  
 ~94% from F/P/T programs; 6% from MAH ←



## 2015 CAEFISS Vaccines and Serious Adverse Events

Below is a chart showing the vaccines suspected of causing the most Serious Adverse Event reports (SAEs) filed with CAEFISS in 2015 compared to the previous 4 years (2011–2014) average.

HepB, Influenza, Meningococcal, Rotavirus and DTap all show increases in serious reports compared to the previous 4 years. Below we discuss some of the possible reasons for these 2015 increases in Serious Adverse events.

### Meningococcal Vaccines

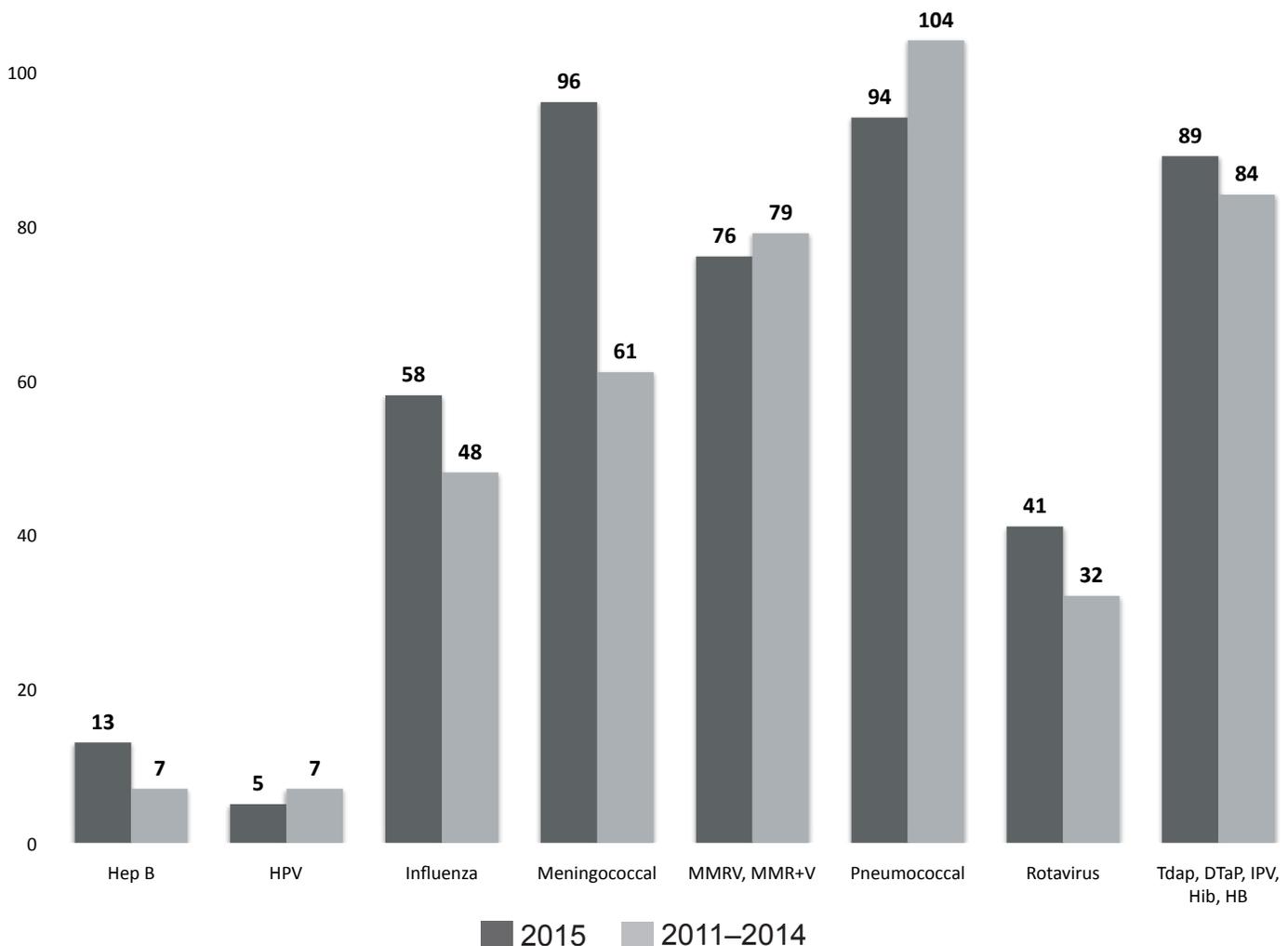
The addition of Bexsero (4CMenB) to the meningococcal vaccine category probably accounts for the more than 1/3 increase in Serious Adverse Events we see in the chart. As we pointed out in our previous report, many of the SAEs in 2014 were for **adult patients** who were also taking the most expensive drug in Canada, Soliris, for certain blood disorders. According to the latest *Immunization Guide* (see

Meningococcal Vaccine, High Risk Groups) a footnote to the chart states “4CMenB [Bexsero] vaccine is not authorized for use in those 17 years of age and older; however, based on limited evidence and expert opinion its use is considered appropriate.”

As previously reported, due to the increased number of SAEs related to Bexsero a safety review was instigated in September of 2015. One year later, results of the Safety Review were finally reported. It appears “the limited evidence and expert opinion” for use of Bexsero in high-risk for Meningococcal infection Soliris patients was not warranted. According to the Summary Safety Review the Potential Safety Issue is “Increased risk of hemolysis and low hemoglobin when patients receiving Soliris were vaccinated with Bexsero”.

Oddly however, it was not the manufacturer of Bexsero who will be changing their product information. The Safety Reviews says: “The manufacturer has updated the Canadian product information for Soliris

120  
CAEFISS SAE reported by suspect Vaccine type for 2015 and 2011-2014 Average



to include the risk of hemolysis with vaccines against *Neisseria meningitidis* serogroup B. To minimize the risk of hemolysis, the manufacturer recommends that patients who are already being treated with Soliris should only be vaccinated when their disease is controlled and the Soliris concentration in the blood is high.” It would seem prudent that this information would also be added to the Bexsero product information sheet, but this is not the case.

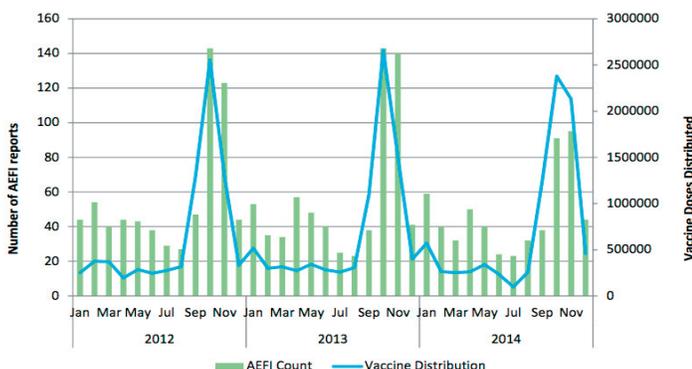
One of the most disconcerting changes to the 2015 CAEFISS Quarter 4 report is that the AEFIs and SAEs for MenB vaccine (Bexsero) are no longer reported separately from the Men C vaccines. Many other vaccines are also being hidden in the new report format. See the Section: Changing Vaccine Categories on page 17 for details.

### Influenza Vaccines

The influenza season runs from September through March. Influenza vaccination campaigns begin in August and September at the same time as school vaccination campaigns. So it is not surprising to see reported in the fourth quarter for the CV database there were 100 reports or 50% of all reports related to influenza vaccines. According to the Q4 CV report text, surveillance teams were “not surprised” by this since in their own words “more awareness” equals more adverse events. That is, vaccine campaigns lead to more vaccines administered which in turn lead to more AEFI reports. Of course this is only common sense; but nevertheless it is an odd divergence from health officials usual mantra that correlation is not causation. In this case, they are saying, that correlation is causation. This is also born out by the chart below from the 2014 Annual Report on Vaccine Safety in Ontario where peaks in the number of vaccines distributed in fall vaccination campaigns clearly correlate with peaks in the number of AEFI reports.

Note also that on the previous page the CAEFISS

**Figure 2.** Number of AEFI reports and publicly funded vaccine distribution<sup>1</sup> in Ontario, by month, 2012-14



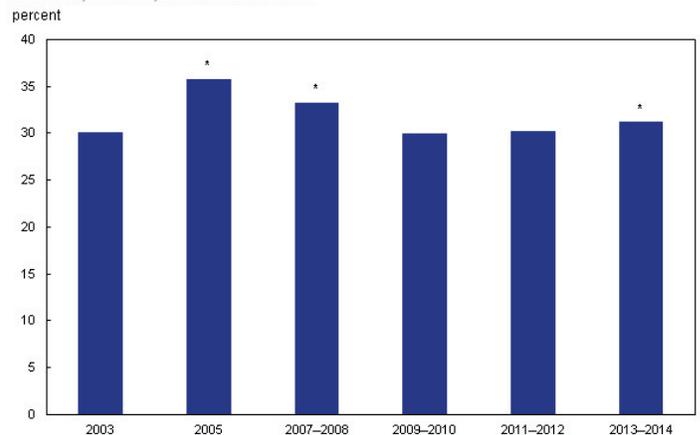
2015 SAE chart shows Influenza serious adverse events (58) increased over the last 4-year average (48) by 21% percent.

None of this is surprising since influenza vaccines rank the highest in number of adjudicated compensations of all vaccines in the US Vaccine Injury Court report. In the latest report for the spring quarter of 2016, influenza vaccine related compensations comprised 45.5% of all compensations, or 80 out of 176 cases in that three month period. Needless to say these cases all involved serious injuries (like GBS) or death.

There are two main reasons flu shots account for so many vaccine injuries. First is that flu shots are not tested for safety. They are essentially experimental drugs. Every spring a new shot is designated based on the best guess of the experts as to what influenza strains will circulate in the coming year. Prior to the beginning of flu shot campaigns in August and September there is little time for field-testing either safety or efficacy like all other vaccines undergo.

The second reason is simply the volume of flu vaccines being administered since they are recommended for everyone, every year. It is the largest single vaccine market. Canada has a current population of approximately 36 million. Approximately 1/3 of the population age 12 and over is vaccinated for flu every year according to StatCan chart below. That’s 12 million doses of flu vaccine per year. Note the chart does not include babies and children under 12 years of age many of whom are also vaccinated for flu.

**Chart 1**  
Age-standardized<sup>1</sup> flu vaccination<sup>2</sup> rates, population aged 12 years and over, Canada, 2003 to 2013–2014



\* significantly different from the 2003 estimate (p<0.05)

1. The data were age-standardized to the age structure of the Canadian respondents of the 2013–2014 Canadian Community Health Survey.

2. Refers to Canadians who received a flu vaccination within the 12 months prior to responding to the survey.

Sources: Statistics Canada, 2003 to 2013–2014, Canadian Community Health Surveys.

Once again we turn to Ontario’s 2014 Vaccine Safety Report to get an idea of how many children suffer the consequences of being vaccinated with influenza vaccines. Their chart is based on a population of 13.7

**Table 1: Number of influenza AEFIs, percent and reporting rate in Ontario, by age group, 2012-2013 to 2014-2015**

Age Category (years) <sup>1</sup>	Count <sup>2</sup>	Percent of AEFIs <sup>2</sup>	Percent of population <sup>3</sup>	Reporting rate (per 100,000 population) <sup>4</sup>
≤4	75	14.3	5.3	3.49
5-9	61	11.6	5.4	2.78
10-17	22	4.2	9.0	0.59
18-49	180	34.2	43.8	1.00
50-64	126	24.0	20.9	1.50
65-79	50	9.5	11.5	1.11
80+	12	2.3	4.2	0.72
<b>Total</b>	<b>526</b>	<b>100.0</b>	<b>100.0</b>	<b>1.29</b>

1 Age - Date of influenza vaccine administration - date of birth  
 2 Total AEFIs = 528 (Two AEFI reports excluded for unknown age)  
 3 Using 2014-2015 population projections (N=13,672,718)  
 4 Reporting rate is calculated using the following denominators: 2012 population estimates for 2012-2013, 2013 for 2013-2014 and 2014 projections for 2014-2015

million, or about 1/3 of Canada’s population. The introduction to this section of the Ontario report says, “Two thirds (65.2%) of all serious AEFIs were 4 years of age or younger.”

In the chart, children under 10 years of age account for 26% of AEFIs reported for influenza vaccine in Ontario. They also have the highest reporting rates at 3.49 per 100,000 population for children 4 years of age or younger and 2.78 per 100,000 population for those between the ages of 5 and 9 years old. Table 2 from the Ontario Report (above right) shows the adverse events and whether they were serious or not. Note that there were 8 serious neurologic events in the table. Also of import is that 20% of AEFI reports included “other severe/unusual events”. These are the post-market “safety signal” events that are not described in the pre-market product literature.

**Find out more about flu shots**

Doctor Mark Geier, who is both an MD and PhD geneticist and worked at the National Health Institute in the US for 10 years has an [excellent video on influenza vaccines](#) and his concerns. Also see [Kelly Crowe’s excellent CBC article](#) on the credibility of how flu deaths are calculated. The VCC website also has many related articles in the [section on Influenza vaccines](#).

One final comment on flu vaccines is necessary. **Many flu vaccines in Canada still contain mercury in the form of Thimerosal.** Influenza vaccines have been removed from the Canadian Immunization Guide. Now the National Advisory Committee on Immunization (NACI) issues an annual [Statement on Seasonal Influenza Vaccine](#) for the current year. You can [download a pdf](#) of the complete document. Included in the report in Appendix A is a table which lists the flu vaccines by name and manufacturer, age of use, ingredients, whether or not they contain Thimerosal and more. This table is reproduced on the following page. Note the difference between single dose and multidose vials. Many healthcare providers use multidose vials as they are less expensive than single dose vials.

**Table 2: Number, percent distribution and reporting rate of influenza vaccine AEFIs in Ontario, by adverse event category, 2012-2013 to 2014-2015**

Adverse event type <sup>1</sup>	Adverse event <sup>2</sup>	Number of AEFI reports <sup>3</sup>	Reporting rate <sup>4</sup>	Percent of all AEFI reports <sup>3</sup>	Number of serious reports	
<b>Injection site reactions</b>	<b>Total</b>	<b>190</b>	<b>1.6</b>	<b>36.2</b>	<b>8</b>	
	Cellulitis	30	0.2	5.7	6	
	Infected Abscess	2	< 0.1	0.4	1	
	Nodule	4	< 0.1	0.8	0	
	<b>Pain/redness/swelling at the injection site <sup>5</sup></b>	<b>162</b>	<b>1.3</b>	<b>30.9</b>	<b>3</b>	
	Pain/redness/swelling extending beyond nearest joint	40	0.3	7.6	1	
	Pain/redness/swelling <4 days <sup>6</sup>	7	0.1	1.3	0	
	Pain/redness/swelling ≥4 days	129	1.1	24.6	2	
	Sterile abscess	2	< 0.1	0.4	0	
	<b>Systemic reactions</b>	<b>Total</b>	<b>156</b>	<b>1.3</b>	<b>29.7</b>	<b>7</b>
Adenopathy/lymphadenopathy		10	0.1	1.9	0	
Arthritis/arthralgia		16	0.1	3	1	
Fever ≥ 38 °C in conjunction with another reportable event		42	0.3	8	6	
Hypotonic-hypo-responsive episode (HIRE)		1	< 0.1	0.2	0	
Parotitis		1	< 0.1	0.2	0	
Persistent crying/screaming		1	< 0.1	0.2	0	
Rash		91	0.8	17.3	1	
Severe vomiting/diarrhea <sup>6</sup>		14	0.1	2.7	1	
Syncope with injury <sup>6</sup>		1	< 0.1	0.2	0	
Thrombocytopenia		1	< 0.1	0.2	0	
<b>Allergic events</b>		<b>Total</b>	<b>145</b>	<b>1.2</b>	<b>27.6</b>	<b>1</b>
		Allergic reaction - skin	111	0.9	21.1	1
	Allergic reaction - other <sup>7</sup>	6	< 0.1	1.1	0	
	Event managed as anaphylaxis <sup>6</sup>	22	0.2	4.2	0	
	Oculo-respiratory syndrome (ORS)	11	0.1	2.1	0	
<b>Neurologic events</b>	<b>Total</b>	<b>32</b>	<b>0.3</b>	<b>6.1</b>	<b>8</b>	
	Anaesthesia/paraesthesia <sup>8</sup>	10	0.1	1.9	2	
	Bell’s palsy	4	< 0.1	0.8	0	
	Convulsions/seizures	9	0.1	1.7	3	
	Encephalopathy/encephalitis	2	< 0.1	0.4	1	
	Guillain-Barré syndrome (GBS)	3	< 0.1	0.6	2	
	Paralysis other than Bell’s palsy	4	< 0.1	0.8	0	
<b>Other severe/unusual events</b>	<b>Total</b>	<b>105</b>	<b>0.9</b>	<b>20.0</b>	<b>8</b>	

**More Information on Vaccines**

You must always know the right questions to ask your healthcare provider. They can tell you the name of the vaccine and whether they use single or multidose vials. Once you have the product name you can download the product monograph from the internet.

If you are interested in the [contents of all vaccines](#) licensed for use in Canada, this information is found in the [Canada Immunization Guide](#), Part 1, Table 1 on page 15. The names of the vaccine products and manufacturer are found within each of the vaccine categories in Part 4. For example, here is the list in the section on Pneumococcal vaccines:

**Pneumococcal conjugate vaccines**

**Prevnar®13** (pneumococcal 13-valent conjugate vaccine, CRM197 protein), Pfizer Canada Inc. (licensee) (Pneu-C-13)  
 The tetanus, diphtheria and non-typeable Haemophilus influenzae carrier proteins used in pneumococcal conjugate vaccine do not confer protection against diphtheria, tetanus or Haemophilus influenzae type b (Hib) disease.

**Pneumococcal polysaccharide 23-valent vaccine**

**PNEUMOVAX®23** (pneumococcal polysaccharide 23-valent vaccine), Merck Canada Inc. (Pneu-P-23)

Pneu-C-7 and Pneu-C-10 vaccines are no longer available in Canada.

You must be prepared to do your own research. Your healthcare provider has less information than you may expect. The VCC website has lots of information.

Appendix A: Characteristics of influenza vaccines available for use in Canada, 2016-2017\*

Manufacturer and Product name	BGP Pharma ULC (Abbott) Influvac®	GSK Fluviral®	Novartis Agriflu®	Novartis Fluad Pediatric™ and Fluad®	Sanofi Pasteur Vaxigrip®	Sanofi Pasteur Fluzone®	Sanofi Pasteur Fluzone® High-Dose	AstraZeneca FluMist® Quadrivalent	GSK Flulaval® Tetra	Sanofi Pasteur Fluzone® Quadrivalent
Vaccine preparations	TIV	TIV	TIV	TIV	TIV	TIV	TIV	LAIV	QIV	QIV
Vaccine type	Inactivated – surface antigen subunit	Inactivated - split virus	Inactivated - subunit	Inactivated - subunit	Inactivated - split virus	Inactivated - split virus	Inactivated - split virus	Live attenuated	Inactivated - split virus	Inactivated - split virus
Route of administration	IM**	IM	IM	IM	IM	IM	IM	Intranasal spray	IM	IM
Authorized ages for use	≥18 years	≥6 months	≥6 months	Pediatric: 6-23 months  Adult: ≥65 years	≥6 months	≥6 months	≥65 years	2-59 years	≥6 months	≥6 months
Antigen content (each of strains)	15 µg HA /0.5 mL dose	15 µg HA /0.5 mL dose	15 µg HA /0.5 mL dose	Pediatric: 7 µg HA /0.25 mL dose  Adult: 15 µg HA /0.5 mL dose	15 µg HA /0.5 mL dose	15 µg HA /0.5 mL dose	60 µg HA /0.5 mL dose	10 <sup>6.5-7.5</sup> FFU of live attenuated reassortants /0.2 mL dose given as 0.1 mL in each nostril	15 µg HA /0.5 mL dose	15 µg HA /0.5 mL dose
Adjuvant	No	No	No	MF59 (oil-in-water emulsion)	No	No	No	No	No	No
Formats available	Single dose pre-filled syringes with luer tip	5 mL multidose vial	5 mL multi-dose vial, single dose pre-filled syringes without a needle	Single dose pre-filled syringes without a needle	5 mL multi-dose vial, single dose ampoule, single-dose pre-filled syringes with or without a needle	5 mL multi-dose vial, single dose ampoule, single-dose pre-filled syringes without a needle	Single dose pre-filled syringes	Prefilled single use glass sprayer	5 mL multidose vial	5 mL multi-dose vial, single dose vials, single-dose pre-filled syringes without attached needle
Post puncture shelf life for multi-dose vials	n/a	28 days	28 days	n/a	7 days	28 days	n/a	n/a	28 days	Up to expiry date indicated on vial label
Thimerosal	No	Yes X	Yes - multi-dose vials only X	No	Yes - multi-dose vials only X	Yes - multi-dose vials only X	No	No	Yes X	Yes - multi-dose vials only X
Antibiotics (traces)	Gentamicin	None	Kanamycin Neomycin	Kanamycin Neomycin	Neomycin	None	No	Gentamicin	None	None
Other clinically relevant non-medicinal ingredients*	Egg protein Chicken protein Formaldehyde CTAB Polysorbate 80	Egg protein α-tocopheryl hydrogen succinate Polysorbate 80 Formaldehyde Ethanol Sodium deoxycholate Sucrose	Egg protein Formaldehyde Polysorbate 80 CTAB	Egg protein Formaldehyde Polysorbate 80 CTAB	Egg protein Formaldehyde Triton X-100	Egg protein Formaldehyde Triton X-100 Gelatin Sucrose	Formaldehyde Egg protein Triton X-100	Egg protein Gelatin hydroxylate Sucrose Arginine Monosodium glutamate	Egg protein α-tocopheryl hydrogen succinate Polysorbate 80 Formaldehyde Ethanol Sodium deoxycholate Sucrose	Egg protein Formaldehyde Triton X-100 Sucrose

\*Full details of the composition of each vaccine authorized for use in Canada and a brief description of its manufacturing process can be found in the product monograph.

\*\*Refer to product monograph for alternate route(s) of administration

### If Ontario can produce useful Vaccine Safety Reports Why Can't the Federal Health Agencies?

This seems a good juncture in this report to point out that the quantity and quality of data in the Ontario Vaccine Safety Reports far exceeds anything the federal government is producing for either the Canada Vigilance adverse events database (with their silly quarterly reports) or the CAEFISS quarterly reports that have been watered down to the point of near uselessness, especially for studying trends.

We recommend the federal government agencies producing the adverse event reports adopt the comprehensive Ontario format, show annual data in their Q4 reports and comparison data from previous quarters and years.

We also recommend that a regular five year schedule be established for publishing a comprehensive *Canadian Immunization Safety Report* that includes AEFI data and analysis from both databases.

## Combining Vaccine Categories in the CAEFISS Reports

The only way to really understand how data has been obscured in the recent 2015 CAEFISS reports is to look at the list of vaccines that appeared in Table 3 in the Q2 Report and compare it to the list in Q4 report.

Table 3 is titled **Vaccines Administered in AEFI Reports**. It is the Table we use to make the SAE suspect vaccine chart like the one on page 14 in this report.

Following is the *verbatim* list of the **30 vaccines** in the Q2 2015 report for Table 3:

Cholera-Ecoli oral (Chol-Ecol-O)  
DTaP-HB-IPV-Hib  
DTaP-Hib  
DTaP-IPV  
DTaP-IPV-Hib  
HA (Hepatitis A)  
HA-Typh (HA Typhoid)  
HAHB (Hepatitis A Hepatitis B)  
HB (Hepatitis B)  
HPV (Human Papilloma Virus)  
Hib (Hemophilus influenza type b)  
Inf (Influenza)  
MMR  
MMR-Var (MMR-Varicella)  
Men (Meningococcal)  
Men-B  
MenC (Men Conjugate)  
MenP (Men Polysaccharide)  
Pneu (Pneumococcal)  
PneuC (Pneu Conjugate)  
PneuP(Pneu Polysaccharide)  
Rota(Rota virus)  
Rab (Rabies)  
Td (Tetanus diphtheria)  
Td-IPV (Adult Tetanus Inactivated Polio)  
Tdap (Adult Tetanus diphtheria acellular Pertussis)  
Tdap-IPV  
Var (Varicella)  
YF (Yellow Fever)  
Zos (Zoster)

Now here is the list from the Q4 2015 Report. It has been reduced to **13 vaccine** categories:

1. DTaP booster
2. DTaP infant series
3. Hepatitis B
4. HPV
5. Influenza
6. MMRV, MMR + V
7. Meningococcal
8. Other vaccines
9. Pneumococcal
10. Rotavirus
11. Tdap booster
12. Travel vaccines
13. Zoster virus

By combining categories, neither the public, nor doctors or other health care providers, can tell which

vaccines are more reactogenic than others in the same category. Before they were combined, one could tell just by looking at the number of reports. For example in the Q2 Report it was noted:

“As shown in Table 1, the proportion of all serious AEFI reports for children one to less than two years of age was higher in Quarter 2 of 2015 than the previous four year average (19 versus 13). This change may be due in part to the recent implementation of new hexavalent vaccines (DTaP-IPV-HB-Hib), which typically have increased AEFI reporting rates. (See Table 3 below).”

Table 3 showed the following SAE Reports for Q2 2015:

DTaP-HB-IPV-Hib	15 SAE
DTaP-Hib	1 SAE
DTaP-IPV	2 SAE
DTaP-IPV-Hib	3 SAE

So the new hexavalent DTAP vaccine—Infanrix Hexa™ by name—accounted for more than twice as many SERIOUS reactions as the other 3 DTaP vaccines for infants combined. We will no longer be able to see this kind of disparity in AEFI reports with the new combined categories.

The same applies to Pneumococcal vaccines. In the Q2 report, Table 3 showed:

Pneu (Pneumococcal)	0 SAE
PneuC (Pneu Conjugate)	25 SAE
PneuP(Pneu Polysaccharide)	1 SAE

The conjugate vaccine appears to be much more reactogenic than the other two. There were no comments in the Q4 report except to state total numbers of AEFI and SAE reports and comparison numbers to previous years. We have no way of knowing if these two vaccines are still causing most AEFIs.

As mentioned above this applies to the Meningococcal vaccines where 4 types are combined in one category now. Chickenpox (Varicella vaccine) is not shown separately anymore either, although you can still search it on the CV database and see 8 cases of vaccine failure resulting in either chicken pox or shingles.

Planning a trip? This also applies to the travel vaccines so you won't be able to see the number of reports for cholera, HepA+B (Twinrix), Td or Yellow Fever.

Whether attempting to decide what vaccines to most safely inject into yourself, your 80 year old mother or your 2 month old child, without this data available informed consent is impossible. And you cannot expect your doctor or public health nurse to have the information if it is no longer being published in the adverse events reports from our health agencies.

## Vaccine Choice Canada Recommendations

Canadians deserve far more timely, accessible, accurate and comprehensible data on vaccine-related adverse event reports.

**Without complete adverse event data available (especially SERIOUS adverse event data) informed consent is impossible.** Further the public cannot expect doctors, pharmacists or public health nurses to have this information if it is no longer being published in the official adverse events reports from our health agencies.

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. **Therefore, we repeat our call for the two databases to be combined, to be publicly accessible and to have Annual Reports issued in a standard format for interpretation.**

AEFI and SAE should be reported as rates per net vaccine doses distributed as they were in the 2006 National Immunization report and still are in the Ontario Vaccine Safety Reports. Each vaccine should be itemized in this way for informed consent purposes.

**While we wait for the databases to be combined, the following changes are necessary:**

Reporting Source of AEFI reports should be included in all Quarterly reports for both databases.

Annual data should be included in Q4 reports for both databases.

Reporting rates based on number of AEFI and SAE reports and vaccine doses administered should be calculated and reported for both databases.

The CV database reports should also include detailed information on age groups affected for AEFI and especially SAE reports, suspect vaccines in reports and the actual adverse events experienced (e.g. neurological, systemic, etc). AEFI and SAE historical data should be supplied for 2013–2014.

The CV database should be returned to functionality for the public so aggregate vaccine data and categories can be searched beyond 1987 and into the present.

Manufacturers should be required to submit complete reports especially with ages and genders of patients shown.

Previously available data on adverse events should be re-included in CAEFISS Quarterly Reports: 1) new combination vaccine categories should be re-expanded, 2) totals and percentages should be included for all data and 3) using the *less than* symbol (<) must stop.

## Questions for MedEffect™ and PHAC

Why did CV & CAEFISS Q4 Quarterly Reports have no annual data included?

Why does it take so long—8 to 9 months—for the two health agencies to publish the quarterly reports? Are the agencies short-staffed for these activities?

Why is it necessary to maintain 2 adverse events databases neither of which is truly accessible by the public?

How can the public be assured that AEFI reports on CAEFISS and CV databases are not duplicates of each other?

## Questions for PHAC

Why was the Vaccine Coverage of Canadian Children 2013 “temporarily removed” from the internet? Is PHAC contemplating releasing a more complete report on the 2015 coverage survey as stated in the removed document?

Why can't the Q4 2015 CAEFISS Report be found with internet search engines?

Why is the Q4 2015 CAEFISS Report not published on the CAEFISS website?

Why are the historical National Vaccine Safety Reports (1993-2014 found on the CAEFISS website) not listed/linked on the new website?

Why has the number of AEFI reports over the last 10 years steadily decreased in Canada despite an increasing population and more vaccines in the childhood vaccine schedule and available in the marketplace?

Why does slide #54 in the 2011 slide show by Barbara Law, Chief of Vaccine Safety at PHAC, show 8500+ more AEFI reports on the CAEFISS database than were reported publicly between 1992 and 2010 in PHAC reports?

Do you plan to publish a National Immunization Report as you did in 2006 and 2014? If so, what year is planned for publication?

## Questions for MedEffect™

Why can we search the Canada Vigilance database for aggregate vaccine information up to 1987, but not beyond that date?

Why and how were the search and/or coding functions changed?

Do you have plans to make it more functional for aggregate and individual vaccine searches?

## Current Routine Schedule for Infants and Children in Canada—Ages 0 to 17 years

Depending on the province or territory, up to **25 vaccines in 61 to 69 doses**. This total includes the following distinct requirements for Aboriginal children: In NWT and Nunavut infants receive BCG (TB vaccine) and HB at birth. Nunavut children also receive Pneu-P at 2-3 years. BCG & Pneu-P are not on the chart below. Also some provinces now use HPV at 9 years of age in a 3-dose regime. View Provincial/Territorial [schedules on-line](#).

### Total by age 17: 23 different vaccines in 61—66 doses

Age at Vaccination	HB & DTaP-IPV -Hib	or DTaP-IPV -Hib-HB	DTaP-IPV or TDaP-IPV	TDaP	Rotavirus Mono or Penta	Pneu-C 13	Men- C-C	Men-C-C or Men-C-ACYW	MMR & V or MMRV	Inf	HPV
Birth	(X)										
4 weeks	X										
6 weeks											
2 months		X	X		X X	X					
4 months		X	X		X	X					
6 months	X	X	X		X		X			X	
12 months					X	X			X		
18 months		X							X	X	
4–6 years			X						(X)	then every year	9-yr (X)
12 years	(X)										X
14–17 years				X				X			X
# vaccines	1		4	3	1 or 1	1	1	1	4	1	1
# doses	1 - 4	5 or 6	1	1	2 or 3	3	1	1	2	2+16	2-3
total vac doses	1- 4	4 or 3	4	3	2 or 3	3	1	1	8	18	2-3

## Vaccines your Healthcare Provider May Offer

### A) Vaccines in the first 12 months of life

#### 1) HB, DTaP, Polio (IPV), and Hib vaccines

- Hepatitis B: • ENGERIX®-B Pediatric dose in combination with DTaP-IPV-Hib:
  - INFANRIX®-IPV/Hib or • PEDIACEL®,
- Or all-in-one DTaP-IPV-Hib-HB
  - INFANRIX hexa™

#### 2) Rotavirus vaccines for gastroenteritis

- ROTARIX®: live, oral, monovalent (Rot-1) or
- RotaTeq®: live, oral, pentavalent (Rot-5)

#### 3) Pneumonia vaccine for *Streptococcus pneumoniae*

- Prevnar®13: 13-valent conjugate (Pneu-C-13)

#### 4) Meningococcal vaccines for C Strain Meningitis

- Monovalent conjugate (Men-C-C)
- Menjugate® oligosaccharide conjugated to CRM<sub>197</sub> protein (Men-C-C-CRM) or
  - NeisVac-C® polysaccharide conjugated to tetanus toxoids (Men-C-C-TT)

(Not on schedule yet, but you may be offered Bexsero™)

#### 5) MMR+V or MMRV

- MMR + V
  - M-M-R®II or • PRIORIX® combined with
  - VARIVAX®III or • VARILRIX®
- MMRV: • PRIORIX-TETRA® or • ProQuad™

#### 6) Influenza vaccine for Flu (see page 17 for mercury content)

- FluViral®, • Agriflu®, • Fluad Pediatric™, • Vaxigrip®,
- Flulaval® Tetra (spray mist), • Fluzone® Quadrivalent

### 2) DTAP Booster

- DTaP-IPV:
  - INFANRIX®-IPV or • QUADRACEL®
- TDaP-IPV
  - ADACEL®-POLIO or • BOOSTRIX®-POLIO

### 3) MMR+V or MMRV Booster

- MMR + V
  - M-M-R®II or • PRIORIX® combined with
  - VARIVAX®III or • VARILRIX®
- MMRV: • PRIORIX-TETRA® or • ProQuad™

### C) Vaccines from 9 years to 17 years

#### 1) Annual Influenza vaccine for Flu same as A6 above

#### 2) Hepatitis B Booster (5 Provinces, 1 Territory)

- ENGERIX®-B or • RECOMBIVAX HB®

#### 3) HPV some Prov/Ter at age 9, some boys also

- CERVARIX® (HPV2) or • GARDASIL® (HPV4) or
- GARDASIL®9 (HPV9)

#### 4) TDap

- ADACEL® or • BOOSTRIX®

#### 5) Meningococcal vaccines

- Monovalent conjugate (Men-C-C)
  - Menjugate® (Men-C-C-CRM) or
  - NeisVac-C® (Men-C-C-TT)
- Quadrivalent conjugate (Men-C-ACYW)
  - Menactra® (Men-C-ACYW-DT)
  - Menveo™ (Men-C-ACYW-CRM)
  - Nimenrix® (Men-C-ACYW-TT)
- Quadrivalent polysaccharide (Men-P-ACYW-135)
  - MENOMUNE® A/C/Y/W-135

(Not on schedule yet, but you may be offered Bexsero™)

### B) Vaccines after 12 months to Age 6

#### 1) Annual Influenza vaccine for Flu same as A6 above