Review of the 2018 *CAEFISS Summary Report*

The ***Vaccine safety surveillance in Canada: Reports to CAEFISS, 2013–2016*** was released to the public in September of 2018. Nelle Maxey wrote this review for Vaccine Choice Canada. Her opinions and analysis are based on what she has learned in her five previous reports on Canada's post-market, adverse events surveillance systems.

Review Summary

The 2018 CAEFISS Summary Report on four years of post-market surveillance of adverse event following immunization is beyond disappointing. **It appears to be a well-calculated attempt to comply with reporting requirements without actually providing meaningful information.**

The report is sloppily written, poorly designed and not transparent. It reports different numbers for the same data, makes statements that are nonsensical and makes declarations that are non-verifiable from the data presented.

Obscuring critical information

The data is reconfigured in five figures and five tables that obscure the limited information on Serious Adverse Events (SAE). This is particularly concerning as 80% of serious events are suffered by children. **As always, the youngest children who receive the most vaccinations in the shortest time period suffered the greatest number of serious adverse events.**

In comparison, an Australian surveillance report shows how data can be reported transparently in well-designed charts and tables, and, more importantly, it shows an emphasis on adverse event data for children. This is completely at odds with the CAEFISS report where our public health officials obscure this data.

Contradictory data reporting

While the report has severely condensed content compared to previous summary reports, a major concern that calls in question its accuracy, is **the contradiction of its own previously published data on numbers of AEFI and SAE reports received.** No one reading the report would be aware of this since **previously published data and trends are completely excluded from the report.**

Low AEFI reporting rates do not equal low AEFI

The self-congratulatory nature of the report is particularly distasteful. A lower AEFI reporting rate of adverse events compared to other countries is not something to be proud of. Quite the opposite in fact, since low reporting rates do not mean that fewer adverse events are actually occurring. Diminished reporting likely reflects an ideology on the part of medical professionals that vaccines are safe, rather than reflecting a genuine attempt to collect and analyze empirical data that could prove otherwise.

While the CAEFISS Summary Report goes to great lengths to distance vaccines from adverse events reports, it then turns around and claims that low reporting rates by inference are a proxy for actual adverse events occurring and therefore somehow prove that vaccines are safe.

Canada is not alone in this disinformation campaign. All internationally established pharmacovigilance schemes use the low reported AEFI numbers against the actual number of vaccine doses to calculate reporting rates and assure us that these low reporting rates mean vaccines are safe. This is illogical, deceptive and dangerous.

One simply cannot use the low reported number of adverse events—a number that represents at most a tiny portion (less than 1%) of actual events—to calculate a reporting rate that is based on all vaccine doses and then conclude that vaccines "have an excellent safety profile".

The actual conclusion

The only conclusion the currently contrived reporting rates are concretely telling the public is that fewer and fewer adverse events are being reported over time in Canada.

We estimate that in the 4 years covered by the CAEFISS report, at a bare minimum, over 1 million adverse events actually occurred. Of these, almost 50 thousand were serious adverse events, the majority experienced by children.

As a final comment, if CAEFISS continues on this downward spiral of barely useful summary reports, trust in the Public Health Agency of Canada and their surveillance system will correspondingly continue to erode.

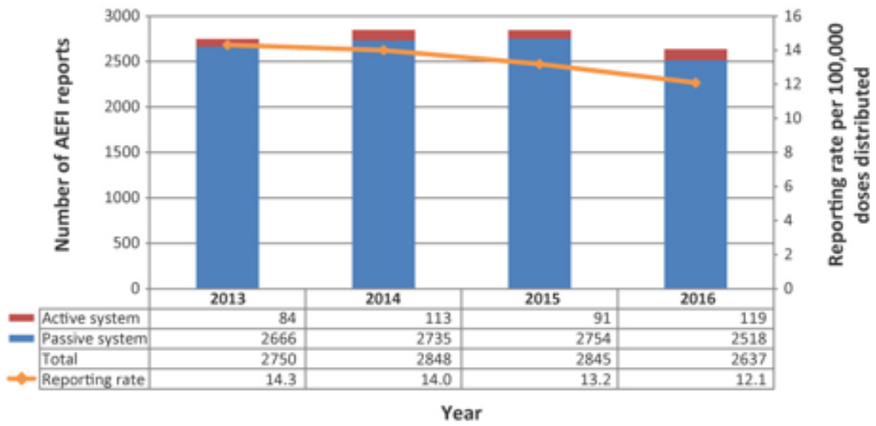
It is becoming increasingly difficult for public interest groups like Vaccine Choice Canada to monitor vaccine safety in Canada since CAEFISS is not fulfilling its mandate. Canadians deserve reports on adverse event data that are meaningful, timely, and entirely transparent.

Part 1. Total Number of AEFI in CAEFISS Reports

The 2018 CAEFISS Summary Report presents results as follows:

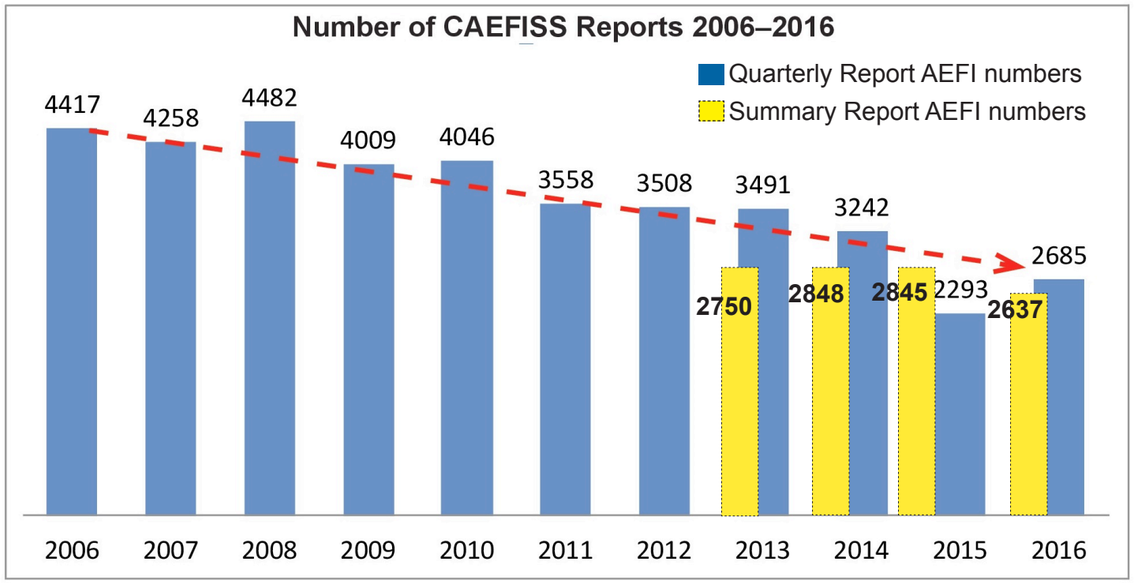
"A total of 11,080 AEFI reports (2,750 AEFI reports in 2013, 2,848 in 2014, 2,845 in 2015 and 2,637 in 2016) from 12 PTs [provinces or territories] were received by CAEFISS during 2013–2016. Over 80 million vaccine doses were distributed, representing reporting rates of 12.1–14.3 per 100,000 doses distributed (Figure 1)."

Figure 1: Total number of adverse events following immunization reports and reporting rate by year, 2013–2016



Immediately noticeable is the fact that annual numbers of reports presented above are very different from those previously reported in *CAEFISS Quarterly Reports*. Here are the direct links to these previous reports: **Q4 2014**, **Q4 2015** and **Q4 2016**. (Note: 2013 data was derived from CAEFISS annual averages in their own reports.)

Below is the chart with data from these previous reports published in ***Vaccine Safety Report 3***. The blue bars in the original chart have been overlaid with the new CAEFISS Summary Report numbers shown by the yellow bars with **new totals** of AEFI reports in bold text.



We have no way of knowing why the 2013–2016 numbers are so different in the current CAEFISS Summary Report from the numbers published in past CAEFISS reports for those years.

Here is the difference between the 2 charts in table form.

YEAR	Previous Report #	2018 Summary #	Difference
2013	3491	2750	741 fewer reports
2014	3242	2848	394 fewer reports
2015	2293	2845	552 more reports
2016	2685	2637	46 fewer reports
4-year totals	**11,711**	**11,080**	**1181 removed & 552 added**

Two questions immediately arise:

1) **2015: Where did the 552 new reports came from?**
2) **2013, 2014 & 2016: Why are a total of 1181 AEFI reports no longer recorded?**

The **data analysis** section of the CAEFISS 2018 Summary Report states:

"All AEFI reports submitted to CAEFISS by August 14, 2017 with a vaccination date from January 1, 2013 through December 31, 2016 were included in this report."

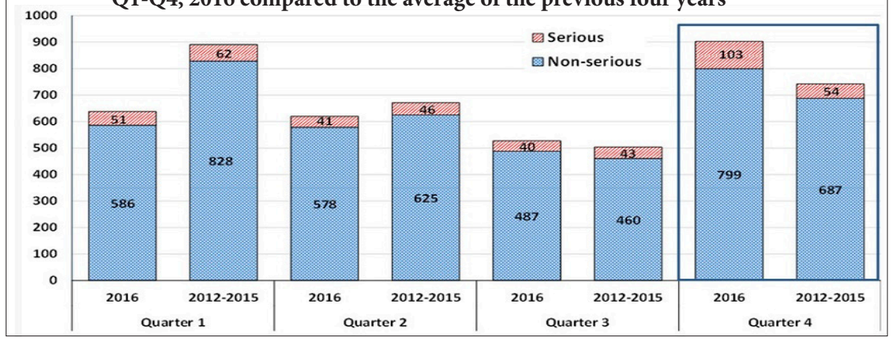
This does not appear to be the case at all since there is so much disagreement between previously published report numbers and current report numbers. Obviously, some secondary filtering of AEFI reports has been done in the new report to change the previously published number of reports. There is no transparency as to what filtering process was used or why it was used.

As we reported in our last ***Vaccine Safety Report 3***, some data dumps occurred in 2016. This could have affected the number of reports in the current summary if the data had been redistributed to the appropriate years. But this does not appear to have happened either. Here is how the **Q4 2016 CAEFISS Report** describes the data dump:

"Technical issues prevented one jurisdiction from providing some data from 2012-2015; these issues were resolved in 2016. Also, one jurisdiction provided a batch of serious reports in Q4 2016 with dates of vaccination dating back to 2013. Together, these resulted in an apparent increase in the number of AEFI reports received in Q4 2016 when compared to previous quarters."

Here is the Q4 2016 Report chart they are referring to in the text above.

Figure 1: Total AEFI reports received, by calendar quarter (serious and non-serious), Q1-Q4, 2016 compared to the average of the previous four years



The annual number of serious reports (red blocks) had remained fairly constant over the five years of this report. We estimate that the two data inputs from two, separate jurisdictions in the fourth quarter of 2016 resulted in around 50 extra serious reports and perhaps 200 extra non-serious reports as shown in Q4 2016 above. However even if this relatively small number of reports (250) were redistributed in the Summary Report to the correct year in which they occurred, they cannot account for 550 **more** reports in 2015. And such redistribution would have increased the number of reports in 2013 & 2014 not reduced their number.

Further each Quarterly Report explains how reports are analyzed as follows:

"All reports are processed and coded using MedDRA, a standardized medical terminology that supports data entry, retrieval, evaluation and presentation of clinical information and further coded with a main reason for reporting through a detailed review of individual case safety reports."

What possible filtering process could have been applied to change the number of these already coded reports? Why does the Summary Report not mention the disparity in AEFI report numbers from those previously published?

Part 2: Total Serious Events in CAEFISS Reports

2013–2016 Quarterly Report SAE numbers

From the Quarterly Reports the total number of Serious (SAE) Reports for 2014, 2015 and 2016 are recorded by CAEFISS as follows. Since there is no published 2013 annual data from CAEFISS, the 2013 numbers were extrapolated from the previous **2014 Summary Report** and the Quarterly Report published averages.

2013 SAE	255 reports	**4-year Total**	**927 SAE reports**
2014 SAE	224 reports	**Annual average**	**232 SAE reports**
2015 SAE	213 reports		
2016 SAE	235 reports		

2018 Summary Report SAE Report numbers

The CAEFISS Quarterly Reports give actual numbers of Serious Adverse Event (SAE) reports each year. **The current Summary Report has no figures or tables that show the annual number or percent of SAE reports or the number or percent of SAE reports for different age groups.** All SAE information presented is for the entire 4-year period and for all age groups combined.

No annual data given	**4-year Total**	**892 SAE reports**
	Annual Average	**223 SAE reports**

The total number of SAE reports is mentioned only twice in the text as **892** and is tabulated as **894** in the text description data for Figure 4. Why this discrepancy within the Summary Report?

Using either number shows fewer SAE reports than shown in the Quarterly Reports above (927–892 or 894 = 35 or 33 fewer reports). Again, the numbers from CAEFISS's own reported data do not match up with the current Summary Report numbers. This indicates that some SAE reports were removed for reasons unknown.

This problem with missing and obscured SAE report numbers is further discussed in Part 4: Comparisons and in the discussion of active and passive reporting in Part 5 of this review.

Part 3: Overview of Figures and Tables in the Results Section of the Summary Report

Reporting Rates are estimates, not true proxies of adverse events

We looked at Figure 1 in the previous section. The reporting rate calculations in that figure are based on doses distributed. Figure 2 and Table 1, which follow, have reporting rates based on population.

The Summary Report explains the difference between the two ways of calculating reporting rates in the **Limitations** section toward the end of the report:

"In addition, the number of doses administered in the population cannot be determined therefore either doses distributed or population statistics are used as the denominator. The use of the doses distributed can underestimate rates, as they do not take wastage into account. Furthermore, doses distributed in one year may not be administered in that same year, further limiting the accuracy of the doses distributed denominator. Despite these limitations, a doses distributed-based denominator for rate calculations was used when possible in this report as a population-based denominator assumes similar distribution of vaccine doses across population subgroups, although this may not be true in all cases."

We comment: **doses administered** could be determined if medical professionals administering vaccines reported this information to the surveillance system as is done in many other countries including the UK and Australia. This reporting is not in place in Canada's adverse events surveillance systems, but should be added, especially for childhood vaccines.

The important differences between the two rate calculation methods are as follows:

1) Doses distributed rates underestimate reporting rates of adverse events.
2) Population based reporting rates are larger, but also have inherent inaccuracy as they do not take into account the actual coverage rate of vaccination within the population.

Figure 2 & Table 1

Figure 2 is not particularly useful although it does establish that babies less than 2 years old experience the most adverse event reports. Table 1 is the only other annual accounting of AEFIs in the entire report and is therefore somewhat useful. Note that neither of these graphics concern themselves with SAE, only with total AEFI reports.

Figure 2: Proportion of adverse events following immunization reports by age group and sex, 2013–2016

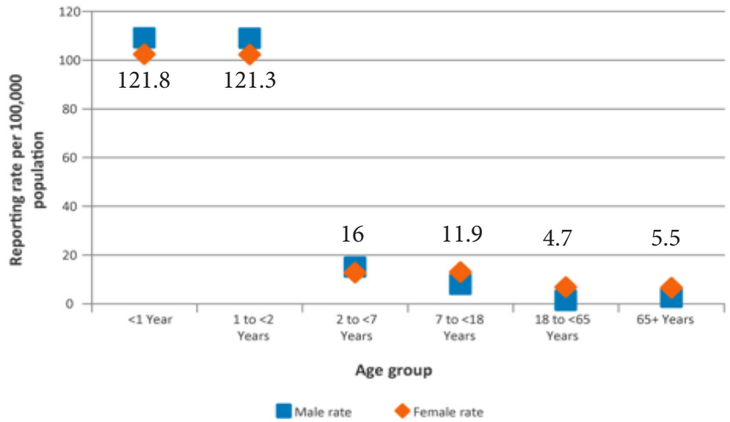


Table 1: Number of adverse events following immunization reports and reporting rate by age group, 2013–2016[a]

Subpopulation by age group	Count of AEFI reports (reporting rate per 100,000 population)				
	2013	2014	2015	2016	All years
<1 year	396 (117.8)	442 (131.2)	386 (114.0)	425 (124.9)	1,649 (121.8)
1 to <2 years	379 (112.6)	399 (117.9)	422 (124.7)	444 (130.6)	1,644 (121.3)
2 to <7 years	313 (18.3)	331 (19.3)	242 (14.1)	213 (12.5)	1,099 (16.0)
7 to <18 years	425 (11.5)	436 (11.8)	453 (12.2)	458 (12.2)	1,772 (11.9)
18 to <65 years	944 (4.8)	1,006 (5.0)	1,028 (5.1)	802 (4.0)	3,780 (4.7)
65+ years	279 (6.0)	225 (4.7)	306 (6.2)	270 (5.3)	1,080 (5.5)
All ages[a]	2,736 (9.0)	2,839 (9.2)	2,837 (9.1)	2,612 (8.3)	11,024 (8.9)

Abbreviation: AEFI, adverse events following immunization
[a] Excluded: 56 reports with missing age

Population based reporting rates in Table 1

We have added the average, 4-year reporting rates from Table 1 to Figure 2 for easier comprehension. The average reporting rate for babies less than 1 year old is given as 121.8 reports for every 100,000 population. The reporting rate for 1 to <2 year olds is essentially the same at 121.3.

This means for every 1000 babies under 2 years of age receiving a vaccine, on average 1.2 were reported to experience an adverse event.

Comparing the population-based reporting rate for all ages for all years in Table 1 to the dose-based rates for all ages and all years in Figure 1 (page 2) shows:

Doses distributed rate—13.4/100,000
Population rate—8.9/ 100,000

This is very odd. Normally, dose-based reporting rates are lower than population-based reporting rates, not higher. There is no discussion or analysis of this anomaly in the report.

Number of SAE Reports for Children

The previous ***2014 Summary Report*** contained Table 3 reproduced below. Total AEFI report numbers and % SAE were given for each year as follows: *"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%)."* Combined with the table below, this data allowed for a comprehensive trend analysis of serious adverse events for children in our **Vaccine Safety Report 2**. Why does the new Summary Report contain no data like this on serious adverse events in children?

Table 3: Annual age-specific AEFI and SAE reporting rates per 100,000 population for vaccines administered

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 2 has detailed information on adverse events; however ,it only gives a percent for SAEs with no numbers. We have done the calculations to add the approximate SAE report numbers and made other comments.

Table 2: Frequency of events and percent of serious events for each primary adverse event following immunization sub-category, 2013–2016

Primary AEFI	Primary AEFI sub-category	Number of Reports (N=11,080)	Serious %	# SAE reports	Subcategory Total SAE % all reports	Our Comments
Allergic or allergic-like events	Anaphylaxis	111	100	**111**	Allergic: 128 SAE 7% of 1795	**4th highest number of SAE reports** *Other* includes hypersensitivity (non-allergic inflammation) and hives. ORS is a reaction to Flu vaccine.
	Other allergic events[a]	1,526	1	**15**		
	Oculo-respiratory syndrome	158	1	**2**		
Infection/ syndrome/ systemic symptoms (ISS)	Fever only	52	21	**12**	ISS: 220 SAE 19.3% of 1141	**Second highest number of SAE reports** Vaccine Failure/Ineffectiveness is a MedDRA Adverse Event category. Infections, rash with fever and systemic events may include vaccine failures following live virus vaccines (like chicken pox and singles) or failures following bacterial vaccines (pneumococcal and meningococcal). In Vaccine Safety Report 3 we found up to 50% of SAE reports for certain vaccines were reported as failures/ineffectiveness.
	Infection	182	34	**62**		
	Influenza-like illness	82	4	**3**		
	Rash with fever and/or other illness	346	5	**17**		
	Syndrome as indicated in AEFI reports (e.g., Kawasaki)	90	79	**71**		
	Systemic (when several body systems are involved)	389	14	**55**		
Neurologic events	Aseptic meningitis	16	81	**13**	Neurological: 277 SAE **46%** of 601	**Highest number of SAEs and highest percent of AEFIs.** Aseptic (nonbacterial) meningitis: inflammation of the brain and spinal column meninges due to immune system attack. Ataxia: lack of voluntary coordination of muscle movements, can include gait abnormality, speech changes and abnormalities in eye movements. Bell's Palsy: one side facial paralysis. Encephalitis: inflammation of the brain. GBS: immune system attacks nerves, paralysis. Seizure: sudden, uncontrolled electrical disturbance in the brain, two or more seizures or recurrent seizures is defined as epilepsy, seizure that lasts longer than five minutes is a medical emergency. *Other* includes migraines.
	Ataxia/cerebellitis[b]	9	67	**6**		
	Bell's palsy	29	0	-		
	Encephalitis / acute disseminated encephalomyelitis (ADEM) / myelitis	25	87	**22**		
	Guillain-Barré syndrome	32	88	**28**		
	Other paralysis lasting more than 1 day	7	43	**3**		
	Seizure	389	48	**186**		
	Other neurologic event[c]	94	20	**19**		
Rash alone	Generalized	1,493	0	-	Rash: Ø SAE 1840 AEFI	
	Localized	225	0	-		
	Location not specified/ extent unknown	122	0	-		
Immunization anxiety	Presyncope	31	3	**1**	Anxiety: 4 SAE 3.3% of 121	
	Syncope	57	2	**1**		
	Other anxiety-related event[d]	33	6	**2**		
Vaccination site reactions	Abscess (infected or sterile)	54	11	**6**	Vac Site: 74 SAE 1.8% of 4149	
	Cellulitis	907	4	**36**		
	Extensive limb swelling[e]	363	1	**4**		
	Pain in the vaccinated limb of 7 days or more	134	1	**1**		
	Other local reaction[f]	2,691	1	**27**		
Vaccination error	Vaccination error	9	0	-		
Other events[g]	Arthralgia	73	5	**4**	Other Events: 170 SAE (Includes 9 Deaths) 7.5% of 1424	**3rd highest number of SAE reports and only noted deaths** Arthralgia/arthritis: joint pain **Rubella vaccine implicated**. Gastrointestinal event: severe vomiting and diarrhea, may result from failure of rotavirus vaccine. Hypotonic-hyporesponsive (HHE) episode: sudden episode of limpness, pallor & unresponsiveness which typically occur within 48 hours of immunization with diphtheria, tetanus, Hib and hepatitis B vaccines. (**Study** of 12 cases following InfanrixHexa® vaccine) Intussusception: Bowel blockage, most common abdominal emergency affecting children under 2 years old. **Risk of Intussusception After Rotavirus Vaccination** study. SIDS & SUDS: See **Miller & Goldman 2001**–SIDS discussion: "Prior to contemporary vaccination programs, 'Crib death' was so infrequent that it was not mentioned in infant mortality statistics… By 1980, SIDS had become the leading cause of postneonatal mortality (deaths of infants from 28 days to one year old) in the United States." Thrombocytopenia: low blood platelet count may result in purpura (bleeding under the skin) **MMR vaccine implicated**
	Arthritis	36	28	**10**		
	Gastrointestinal event	549	3	**17**		
	Hypotonic-hyporesponsive episode	74	26	**19**		
	Intussusception	29	83	**24**		
	Anaesthesia/Paraesthesia	203	2	**4**		
	Parotitis	9	0	-		
	Persistent crying	72	3	**2**		
	Sudden infant death syndrome	6	100	**6**		
	Sudden unexpected/ unexplained death syndrome	3	100	**3**		
	Thrombocytopenia	43	81	**35**		
	Other events[h]	327	14	**46**		

VCC ADDITIONS TO TABLE 2

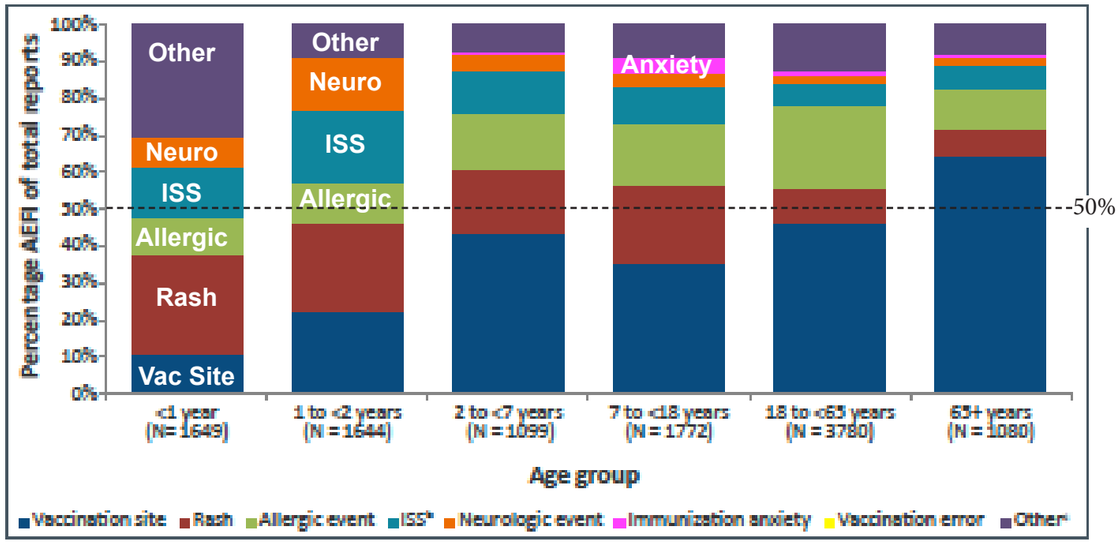
The immunization anxiety AEFI listed (basically fainting & weakness) are also the **2nd most common adverse reactions to HPV vaccines**. See Figure 3 pink bands in the age groups receiving HPV vaccines. These vaccine reactions are now apparently defined away as "anxiety".

"Pediatricians are generally aware that DTaP vaccine can cause large local inflammatory reactions, especially after the fifth (preschool) dose. Particularly large reactions invite confusion with bacterial cellulitis. Studies of the preschool booster documented that 19.3% to 33% of children have a large local reaction (redness and/or swelling 2 inches in diameter or greater), and 1% to 2% have extensive limb swelling from shoulder to elbow." [modified quote, see link]

Other events-other events include lymphadenopathy

Figure 3 in the report takes the main categories listed in Table 2 and breaks them into age groups. We added labels in some columns for easier understanding.

Figure 3: Percentage of adverse events following immunization reported by age group, 2013–2016[a]



The ***text description*** that accompanies this chart (in the on-line Report only) has the following table of data.

Primary AEFI	Age group and Percentage of AEFI reports					
	<1 year (N= 1649)	1 to <2 years (N = 1644)	2 to <7 years (N = 1099)	7 to <18 years (N = 1772)	18 to <65 years (N = 3780)	65+ years (N = 1080)
Allergic event	10.4%	11.2%	15.0%	16.8%	22.4%	11.0%
ISS	13.5	19.8	11.3	10.0	5.8	6.2
Immuniza. Anxiety	0.1	0.1	0.5	4.0	1.0	0.7
Neurologic event	8.1	14.2	4.6	3.7	2.3	2.4
Other	30.2	8.5	7.2	8.9	12.3	7.9
Rash	26.7	23.6	17.9	20.7	9.6	7.4
Vaccination error	0.2	0.1	0.2	0.1	0.0	0.1
Vaccination site	10.9	22.6	43.3	35.9	46.7	64.4

This information should have been included in Figure 3 as it is necessary to really understand the percentage amounts represented by the colored bars. For example, more than half of the adverse event reports for children less than 2 years old were in categories containing serious adverse events, including deaths.

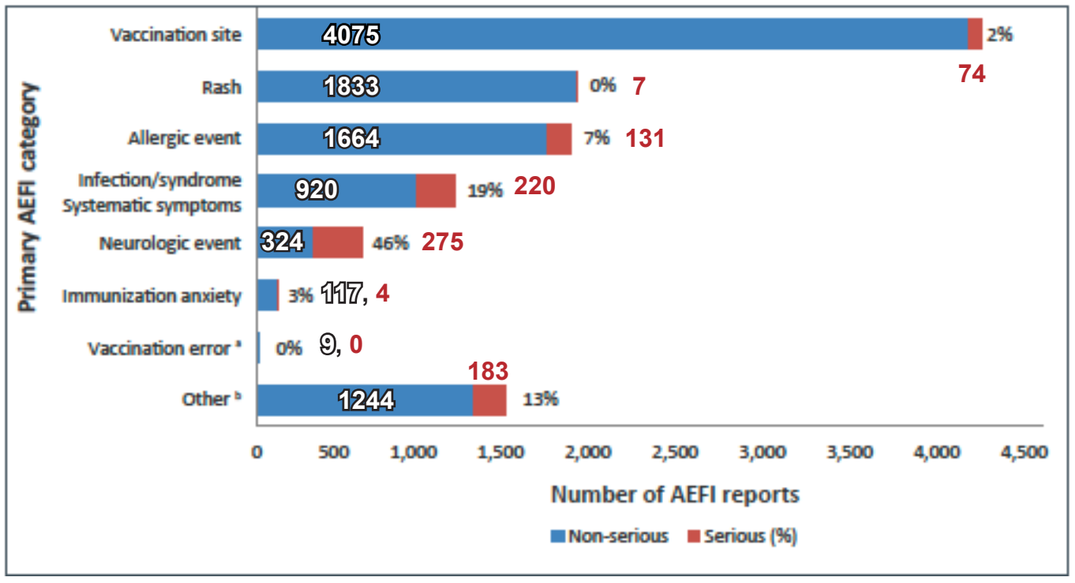
For babies <1 year old nearly one third (30.2%) of the AEFI reports are in the "Other" category which includes serious events like SIDS and SUDs deaths, intussusception that requires surgery, thrombocytopenia, arthritis, HHE episodes and so forth. 13.5% of reports were ISS (Infections/Syndromes/Systemic events) including serious syndromes like Kawasaki's disease and cardiac events. 10% of the reported events were allergic, which includes life-threatening anaphylactic shock. Neurologic events while only accounting for 8% of reports had the highest percentages of serious events in Table 2 including seizures, encephalitis (brain swelling) and GBS (paralysis and death). For babies between 1 and 2 years old, almost 20% of events were Infections/Syndromes/Systemic (ISS) events, over 14% were neurologic events, over 11% were allergic and 8.5% were Other. **All serious reports for children should be fully documented in a meaningful way, not obscured as they are here.**

Figure 4 summarizes the sub-category information in Table 2. **We have added the SAE report numbers from the text description to Figure 4 below.** Text descriptions are not available in the pdf version of the report, only in the on-line version. This text description contains the **only occurrence of SAE report numbers in the entire Summary Report**. It counts **894 SAE** reports, not 892 as reported twice in the report text.

Figure 4: Primary adverse event following immunization category by seriousness, 2013–2016

Primary adverse events	Non-serious	Serious	Total AEFI	% Serious
Other	1244	183	1427	13
Vaccination error	9	0	9	0
Immunization anxiety	117	4	121	3
Neurologic event	324	275	599	46
Infection / Syndrome / Systematic symptoms (ISS)	920	220	1140	19
Allergic event	1664	131	1795	7
Rash	1833	7	1840	0
Vaccination site	4075	74	4149	2
Total	10186	**894**	**11080**	8%

Figure 4: Primary adverse event following immunization category by seriousness, 2013–2016 (with numbers added)



If we calculate the percent of SAE reports from the text description above we see that 894 is 8% of 11,080, the total number of AEFI reports. This confirms the text in the report, which says that 92% of all AEFI reports are non-serious reports and 8% are serious.

Active and Passive Reporting

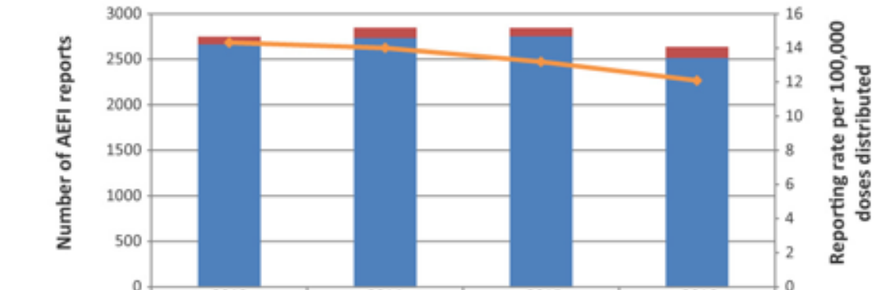
A portion of the Serious reports are called Active reports as opposed to the Passive serious reports received from the various health authorities in Canada. The Active SAE reports come from the IMPACT surveillance system located in 12 pediatric hospitals in Canada. Because these children are hospitalized, by definition all Active reports from IMPACT are serious reports for children.

The text following Figure 4 has two statements of interest to us. The first statement appears to be wrong:

"For children less than 18 years of age, 7% (n=710) of all submitted AEFI reports were through active surveillance.

This statement makes no sense. If we return to Figure 1, where Active and Passive reports are delineated, we see that there are only 407 Active reports in total. Therefore it is not possible that 710 reports were submitted "through active surveillance".

Figure 1: Total number of adverse events following immunization reports and reporting rate by year, 2013–2016



	2013	2014	2015	2016
Active system	84	113	91	119
Passive system	2666	2735	2754	2518
Total	2750	2848	2845	2637
Reporting rate	14.3	14.0	13.2	12.1

Total Active reports: 84 + 113 + 91 + 119 = 407

We know from Table 1 (on page 5) that a total of 6164 AEFI reports were submitted for children <18 years old (1649 +1644 +1099 +1772 = 6164). 7% of the 6164 AEFI reports for children would be 572 active reports. This is also impossible since Figure 1 clearly records only 407 Active reports for children. **So both the number and percent in the first statement are wrong.** The second statement of interest following Figure 4 is:

"Even though the proportion is small [referring to the percent of active reports in first statement above] *they represented 56% (n=398) of all serious AEFI reports submitted for this age group, reflecting the contribution of the hospital-based active surveillance system."*

This statement gives us the only clue as to the total number of SAE Reports for children, which is not found anywhere in the report. It also suggests where the number 710 in the first statement above came from. If 398 reports represents 56% of all SAE reports for children, then the total number of SAE reports would be 710. (56% of 710 = 398.)

There is another problem with the second statement however. Table 1 shows there were 407 Active reports for children. The second statement above says the number is 398, so that is 9 fewer serious active reports than recorded in Figure 1. Why this discrepancy? Which number is wrong?

The first statement above would have to be re-written as follows so it makes sense with the other numbers contained in the Summary Report:

"For children less than 18 years of age, either 6.6% (n=407) or 6.5% (n=398) of all submitted AEFI reports (n=6164) were through active surveillance."

All in all, it is very frustrating to glean any information about serious adverse events for children from the data as presented in this report.

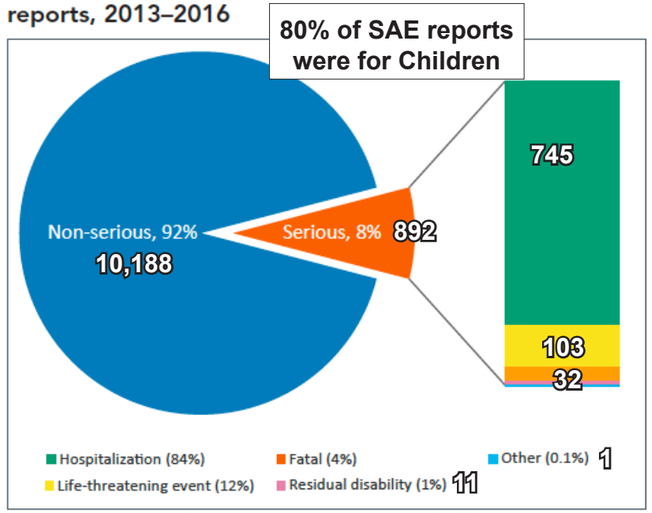
Table 3 & 4 concern health care utilization and outcomes of AEFI reports. We compare those to previous CAEFISS reports in Part 4 (page 12) to see longer term trends which are not shown in this report.

The report's "analysis" of Serious Adverse Events continues with Figure 5 which is a simple pie chart with SAE outcomes broken out. The text preceding this figure tells us: *"Overall there were 892 SAE reports out of over 80 million vaccine doses distributed during the reporting period. This represents a rate of 1.1/100,000 doses distributed and 8% of all AEFI reports over the four year time period (range: 1.0 to 1.2 reports per 100,000 doses distributed). Figure 5 shows the proportion of SAE reports resulting from hospitalization (n=745), life threatening events (n=103), fatal outcome (n=32), residual disability (n=11) and other reasons (n=1)."*

For easier comprehension, we have added the numbers from the above text to Figure 5 below.

Aside from the fact the tabulation of SAEs for Figure 4 said there were **894** SAEs (not 892), the numbers and percents in the text seem accurate in relation to the Outcome table preceding this figure.

Figure 5: Classification of serious adverse events reports, 2013–2016



The text following Figure 5 says "*The majority of SAEs were in children and adolescents less than 18 years of age (80%).*" This confirms the total number of SAEs reports for children that we calculated from the quote from Figure 4 of 710 total SAE reports for children. (80% of 892 = 710.)

The text also says that "over half" were experienced in children less than 2 years of age. Since no number is revealed, all we know is that children less than 2 experienced more than 355 SAEs, although we don't know which type. The text continues: "*Among the SAE reports, the most frequently reported primary AEFI was seizure (20.1%), followed by anaphylaxis (12.4%).*"

In terms of an SAE reporting rate of "1.1/100,000 doses distributed" this is for all ages groups. It is also important to note a child receives up to 36 doses of various combination and monovalent vaccines by the time they are 18 years old, if they are vaccinated to the current vaccine program schedules in the jurisdiction they reside in. This increases the individual risk of any child experiencing an SAE beyond the dose-based reporting rate.

18 deaths reported in Children
9 deaths <1
7 deaths 1 to < 2
2 deaths 2 to < 7
13 deaths reported in Adults
6 deaths in adults 18 to 65
7 deaths in adults over 65

How Deaths were Reported

The text following Figure 5 discusses the SAE reports that recorded deaths as follows:

"All 32 reports of death underwent a careful review and all were found not to be attributable to the vaccines administered. Nine of these (28%) were reported in the youngest age group (less than one year of age); of which six were reported as sudden infant death syndrome (SIDS) and three as resulting from other underlying medical conditions (cerebral infarction, cardiac arrest and complications during nasogastric feeding). Seven deaths were reported in the one to less than two years old age group, of which three were reported as sudden unexplained death syndrome (SUDS), three due to infection not related to the administered vaccine(s) (pneumococcal, streptococcus pneumonia/staphylococcus, necrotizing encephalitis) and one due to a pre-existing condition (brain injury). There were two deaths due to underlying conditions (congenital disease and severe brain injury during birth) reported in the two to less than seven years old age group, and one death due to pre-existing condition (epilepsy) in the seven to less than 18 years old age group. The remaining 13 deaths were reported in adults: six in the 18 to 65 year old age group and seven in the 65+ year old age group (age range: 49–93 years), all of whom had pre-existing medical conditions. The listed causes of death included cardiovascular diseases (myocardial infarction, ischemic heart disease and atherosclerosis), lung disease (chronic obstructive pulmonary disease, asthma), central nervous system disease (dementia, H1N1 encephalitis, cerebral palsy and intracranial empyema), malignancy (lung and breast cancer), immunosuppression and diabetes mellitus."

Whether any of these deaths were related to vaccines remains for us an open question, especially since SIDS and SUDS deaths have been documented to occur following some vaccines. The other question we pose regards vaccinating those with "underlying medical conditions". Is it really a good idea to vaccinate children and adults who are unwell for the great variety of reasons mentioned in the text above? For example, how did the 'experts' decide on medical case review that the deaths of the two babies less than one year old who suffered a stroke and a cardiac arrest were unrelated to a vaccine? Of course, both these questions remain unanswered.

The final table in the report, Table 5, regards the vaccines themselves. It only lists the top 10 vaccines found in AEFI reports. Further it only itemizes serious reports rates for vaccines given alone! This necessarily excludes vital information on most childhood vaccines since almost all are given in combination at well-baby visits.

This is a greatly reduced table compared to the previous **2014 CAEFISS Report**. In that report, Table 7 labels and lists all 18 vaccines from publicly funded programs and then 11 more vaccines—2 that are special use (BCG and Rabies) and 9 not publicly funded vaccines—for a total of 29 vaccines. Aside from that, the most noticeable omission in Table 5 below compared to the earlier table is **the number and percent of SAE reports** for the given vaccines. Why has this data been omitted?

As an example, Men C conjugate vaccine (MenCC) is **given to all Canadian babies** in one or two doses in the first year of life in combination with other childhood vaccines; so it is rarely administered alone. In Table 5 below only 2% of AEFI reports show it was administered alone. So why would we be concerned with the number of SAE reports for those few, single administrations when the real issue is how many babies experienced serious adverse events when this vaccine is administered according to schedule with other childhood vaccines? The 2014 CAEFISS Report Table 7 shows there were 468 AEFI annual reports for this vaccine, the reporting rate was 85.2/100,000 doses and that 61 reports or **13% reported SAEs**. In the current CAEFISS Report Table 5, the AEFI reporting rate for Men CC has increased to 91.6/100,000 doses, but we have no idea how many SAEs were reported or what percent of the total AEFI reports for this vaccine had serious events noted.

Table 5: List of top ten vaccines for total adverse event reports following immunization and total number of reports and serious adverse events when vaccine administered alone, 2013–2016

Vaccine group	Vaccine trade name	Reporting rate per 100,00 doses distributed		Reports vaccine administered alone		Reports of SAEs from vaccine administered alone[a]	
		N	%	N	%	N	Rate[a]
Meningococcal serogroup C conjugate	Meningitec® Menjugate® Neis Vac-C®	1,346	91.6	33	2	4	0.3
Diphtheria, tetanus toxoid, acellular pertussis, inactivated poliomyelitis	Quadracel® Infanrix™-IPV	167	76.8	92	55	4	1.8
Diphtheria, tetanus toxoid, acellular pertussis, hepatitis B, inactivated poliomyelitis, haemophilus type b	Infanrix hexa™	462	65.9	35	8	2	0.3
Pneumococcal conjugate	Prevnar® Synflorix™ Prevnar® 13	2,098	64.4	64	3	5	0.2
Measles, mumps, rubella, varicella	Priorix-Tetra™ Proquad™	1,075	59.8	86	8	11	0.6
Meningococcal B	Bexsero®	212	57.1	160	75	17	4.6
Haemophilus influenzae type b conjugate	ACT-HIB® Hiberix® Liquid PedvaxHib®	39	45.9	4	10	0	0.0
Rabies	Imovax® Rabies RabAvert®	80	43.2	64	80	4	2.2
Pneumococcal polysaccharide	Pneumo® 23 Pneumovax® 23	915	42.9	452	50	28	1.3
Diphtheria, tetanus toxoid, acellular pertussis, inactivated poliomyelitis, Haemophilus type b	Pediacel® Infanrix™ - IPV/HIB Pentacel®	1,512	40.7	422	28	38	1.0

Of the top ten vaccines that CAEFISS has chosen to show us in Table 5, four (marked with a grey box) are not in the **childhood vaccine schedules** in any jurisdiction. Of these vaccines, MenB (Bexsero®) and Hib alone (not in combination DTaP vaccines) are not publicly funded. Rabies is a special purpose vaccine and pneumococcal polysaccharide is an adult vaccine; both are publicly funded. While these four are obviously reactogenic vaccines and therefore worthy of noting, aside from the adult pneumococcal vaccine none are in widespread use as you can see from the AEFI report numbers.

Only six childhood vaccines are on the list. In the 2014 report that lists all childhood vaccines, MMR (29%SAE) and Varicella (16%SAE) given separately had higher AEFI reporting rates than MMRV (42% SAE) at 68.2, 74 and 58.7 per 100,000 doses respectively. Also the pneumococcal conjugate vaccine for children had a high reporting rate of 56.8/100,000 doses with 11.4% of reports for serious events. And the rotavirus vaccine had 21% SAE reports. None of this information is available in the current report's 'top ten' list.

All the data on childhood vaccines should be available to the public in the CAEFISS reports.

Part 3: Comparisons

A. Comparing CAEFISS Summary Reports

The last three CAEFISS summary surveillance reports cover 26 years of postmarket surveillance of AEFI data. ***The Canadian National Report on Immunization, 2006*** (archived) has 14 years of data from 1992–2004. ***The Adverse events following immunization in Canada: 2012*** report (published in 2014) has 8 years of data from 2005–2012 and the ***2018 CAEFISS Summary Report*** has 4 years of data from 2013–2016.

There is no comparison that can be made to quality and quantity of data in the two previous reports and the current report we are reviewing here. This is especially apparent in terms of serious adverse event (SAE) data as we have pointed out. We suggest that those interested take a quick scan through the two previous reports to see the detail and explanations that were offered in those reports, compared to what is presented in the current report. It appears that in the face of "vaccine hesitancy", instead of a more fulsome disclosure of vaccine injury data, the Public Health Agency of Canada has decided to limit and obscure data. This unfortunately only increases the lack of public trust in the surveillance system leading to more hesitancy.

As a final exercise, we can make the following comparisons that show some long term trends in Canadian adverse events following immunization data. First is the reported outcome of those experiencing an adverse event. The most worrying outcome trend is fewer vacinees are fully recovering from adverse events.

Outcome	2004	2012	2013-2016	13 Year Trend 2004 to 2016
Full Recovery	84%	67.8%	76%	–8%
Not Yet Recovered	9%	16.2%	18%	+9%
Permanent Disability/Incapacity	6%	0%	<1%	–5%
Death	0.3%	0.1%	<1%	stable
Unknown/missing	<1%	15.8%	5%	up and down

Health care utilization for AEFIs is generally increasing. Physician visits of course are not represented here as PHAC does not monitor these. In the 13 years represented here hospital admission is up 2%, emergency department use is up 12%, non-urgent outpatient use is up 6%, and no medical attention is down 5%.

Health Care Utilization	2004	2012	2013–2016	13 Year Trend 2004 to 2016
Hospital admission	5%	5.2%	7%	+2%
Prolongation of hospital stay	–	0.1%	<1%	stable
Emergency Department assessment	7%	17.9%	19%	+12%
Non-urgent outpatient visit	31%	35.9%	37%	+6%
Health professional advice	–	5%	4%	–1%
No medical attention	28%	24.5%	23%	–5%
Not indicated/unknown	28%	11.4%	10%	–18%

For reports by age group, the most concerning data is that children suffered 77% of Serious Adverse Events per the data given in 2012 and 80% in the current Summary Report.

AGE Group	AEFI 2004	AEFI (SAE) 2012	AEFI (SAE) 2013–2016	13 Year Trend 2004 to 2016
< 1 year	12.3%	14% (24%)	15%	3% increase
1 to <2 years	17.2%	16% (32%)	15%	2% decrease
2 to <7 years	14.5%	14% (12%)	10%	4.5% decrease
7 to <18 years	12.5%	14% (9%)	16%	3.5% increase
All children	**56.5%**	**58% (77%)**	**56%(80%)**	AEFI stable, SAE increasing
18 to< 65	31.5%	32% (14%)	34%	2.5% increase
65 + years	6.8%	9% (8%)	10%	3.2% increase

SAE information for children is readily available in the CAEFISS Quarterly reports and should be included in the Summary Report. Below is a comparison of 2012 SAE data with Quarterly Reports for 2015 & 2016 cumulative SAE data to show a 5 year trend.

AGE Group	2012 SAE	2015 SAE	2016 SAE	5 year Trend 2012 to 2016
< 1 year	24%	32%	33%	9% increase
1 to <2 years	32%	31%	28%	4% decrease
2 to <7 years	12%	11%	13%	1% increase
7 to <18 years	9%	8%	11%	2% increase
All children	**77%**	**82%**	**85%**	**8% increase in SAE**

According to Quarterly Reports, in 2016, infants less than 1 year old suffered 33% and children less than 2 suffered 28% of Serious Adverse Events for a total of 61%. This information is not available in the CAEFISS Summary Report.

B. Comparing Canadian and Australian Surveillance of Adverse Events Reports

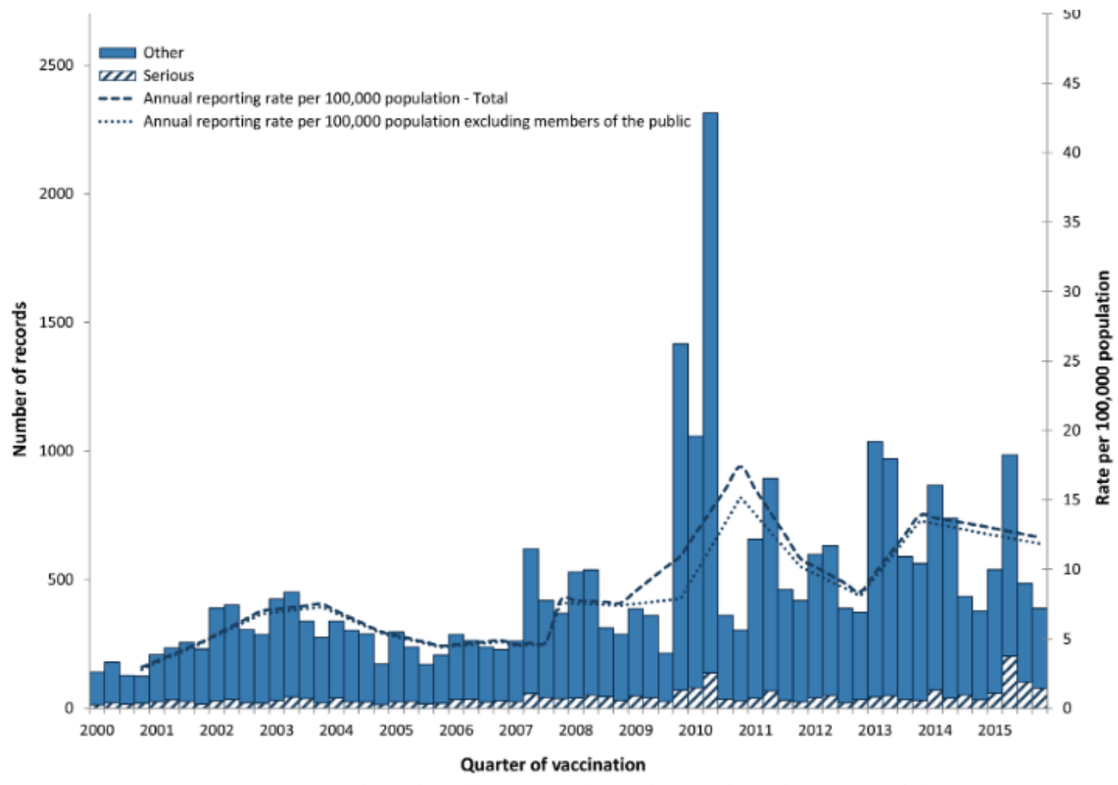
The first distinction between Australia and Canada reporting is that Australia reports on an annual basis. While Canada did issue Quarterly CAEFISS Reports for 2014, 2015 and 2016, there are currently no published Quarterly reports for 2017 on the CAEFISS website. Since we are into the last quarter of 2018, we would expect to see at least the reports for the first and second Quarter of 2017 by now. We do hope that CAEFISS intends to continue with the Quarterly Reports. We also hope the Summary Reports in the future will contain better information and be published more regularly. Australia would be a good model to follow for more thorough post market surveillance reports of AEFIs in Canada.

Below are charts and tables from the **Annual report: surveillance of adverse events following immunization in Australia, 2015**. Here is a quote from the opening of the report: *"Reports summarizing national AEFI surveillance data have been published regularly since 2003. Trends in reported adverse events following immunization are heavily influenced by changes to vaccine funding and availability provided through the National Immunization Program (NIP). These changes impact on the interpretation of trend data and have been described in detail in reports published since 2003. Appendix 1 shows the chronological listing of the changes."*

In Canada's reports there is little acknowledgement that adverse event reporting trends are "heavily influenced" by publicly funded vaccine programs nor is a comprehensive listing of chronological changes to Canada's immunization programs available in the reports (nor anywhere on Health Canada's websites that we have been able to find).

The first figure in the Australian report shows the number of AEFI and SAE reports for all age groups over the entire 15 years of data collection and reporting rates for medical professionals separate from rates that include reports from the public.

Figure 1: Adverse events following immunization, ADRS database, 2000 to 2015, by quarter of vaccination



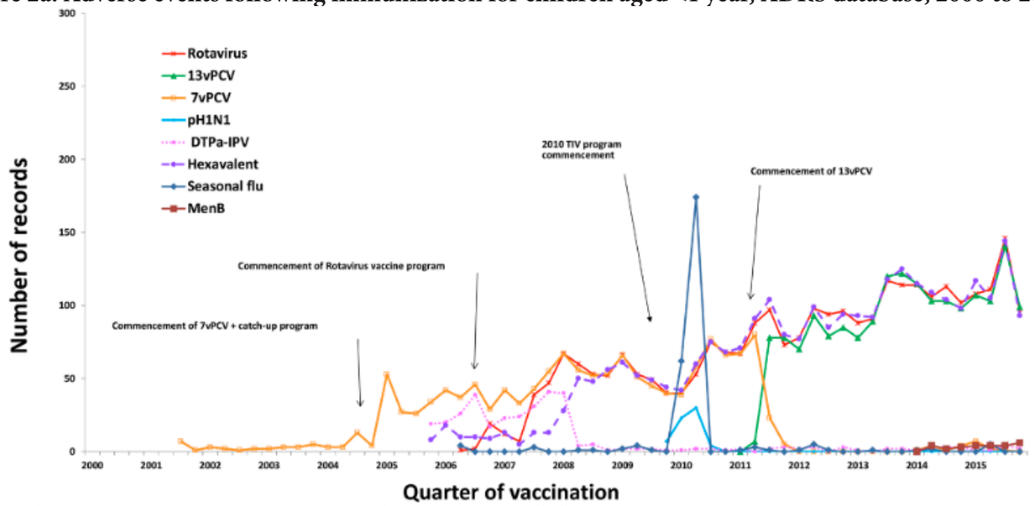
It is very easy to see the report trends in this all-ages bar chart. The number of reports and the reporting rate of AEFI/SAE has increased since 2000. The report discusses the changes to the vaccine programs that have lead to

these increases.

The large number of AEFI reports in 2010 was the result of two influenza vaccines. First the pandemic H1N1 vaccine was administered and had many adverse events reported. Second, in 2010 Australia suffered a **catastrophic failure of a trivalent influenza vaccine (TIV)** mandated for children under 10. It was withdrawn from the market when the safety signal was noted, but it accounts for the 2010 peak seen in this chart and other charts below. (Note that Australia does not hide the H1N1 data unlike Canada. In the **2014 CAEFISS Summary Report** one can read [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***.")

The all ages figure above is followed by two figures, one with reporting rates for children less than 1 year of age and one for children from one year to less than 7 years of age. The charts list the vaccines received by the age group under consideration. Obviously the Australian Department of Health is aware that the most concerning AEFI/SAE data is for the most highly vaccinated population—children from birth to pre-school age—and therefore highlights this data in their reports. This approach emphasizes our concern that the Canadian Summary Report deletes or obscures this very information. Also note that Australian children are less vaccinated than Canadian children, yet no serious epidemics of vaccine preventable diseases have occurred. In fact the worst public health crisis was caused by a vaccine.

Figure 2a: Adverse events following immunization for children aged <1 year, ADRS database, 2000 to 2015



*safety signal for fever and febrile convulsion found to be due to Fluvax 2010 TIV in children.

DTPa-IPV and DTPa-IPV HepB Hib (hexavalent) vaccines were introduced in the NIP schedule in November 2005; rotavirus (RotaTeq® and Rotarix®) vaccines on 1 July 2007; pH1Ni influenza vaccine for children 6 months to 10 years in December 2009; seasonal trivalent influenza vaccine in 2010 which was an extension of existing adult and Aboriginal and Torres Strait Islander Peoples programs to at-risk populations; and the 13-valent pneumococcal conjugate vaccine (13vPCV) on July 2011. Also MenB vaccine is recommended for use in those with increased risk of invasive meningococcal disease and is not currently funded under NIP.

We find these comprehensive line charts very clear and easy to understand. Further, the chart notes link the vaccines added to schedules that are influencing the reporting rates.

It is very clear from this line chart that three childhood vaccines in Australia—rotavirus, 13-valent pneumococcal and hexavalent DTaP—are the main contributors to the rising number of adverse event reports in the less than 1 year age group in recent years.

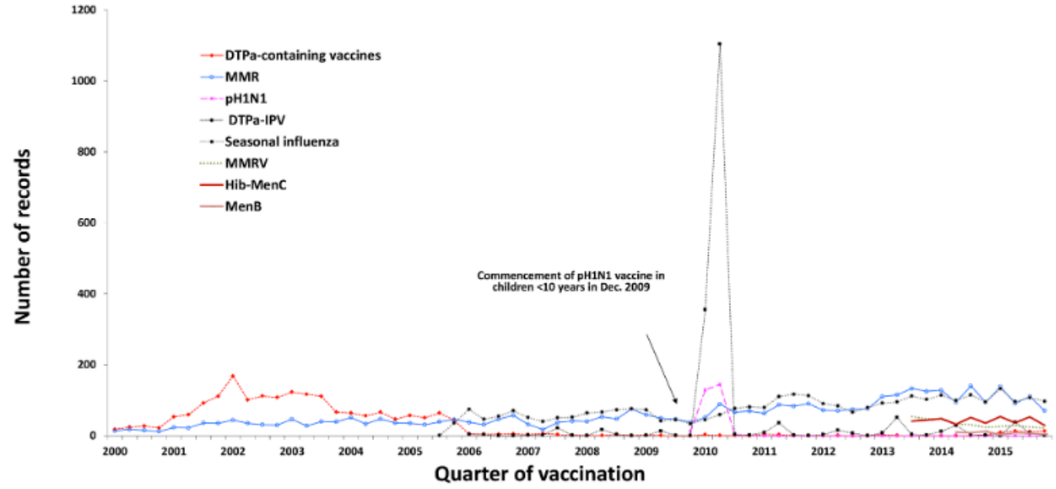
The green line represents the 13-valent pneumococcal vaccine. The gold line is the 7-valent pneumococcal vaccine that has now dropped out of use. But it is apparent that this bacterial vaccine, whether 7-valent or 13-valent, has always been highly reactogenic for infants.

The red line is the rotavirus vaccine which has climbed steadily since its introduction in 2006.

The purple dotted line is the hexavalent DTaP vaccine (InfanrixHexa®) that came into use in 2006. By 2008 it had replaced the pink dotted line of DTaP-IPV, and has climbed steadily since. While all 3 of these vaccine report numbers fell in 2015, it will be interesting to see what has transpired when the 2016 report is published.

The next figure in the report is for the 1 year old to less than 7 year old population. It includes administration of the MMR or MMRV vaccine as well as booster DTaP and the MenC-Hib. This last vaccine is not used in Canada. We offer Hib in combination with DTaP vaccines and MenC is a monovalent vaccine given to less <1 year olds in four jurisdictions and to 1 year olds in all jurisdictions.

Figure 2b: Adverse events following immunization for children aged 1 to <7 years in frequently reported vaccines, ADRS database, 2000 to 2015, by quarter of vaccination



* safety signal for fever and febrile convulsion found to be due to bioCSL Fluvax 2010 TIV in children.
DTPa-IPV was introduced into the NIP schedule in November 2005 replacing DTPa and OPV; seasonal trivalent influenza vaccine in 2010 which was an extension of existing adult and Aboriginal and Torres Strait Islander Peoples programs to at-risk populations; MMRV and Hib–MenC vaccines on July 2013, and HPV program extended to boys in February 2013. Also, MenB vaccine is recommended for use in those with increased risk of invasive meningococcal disease and is not currently funded under the NIP.

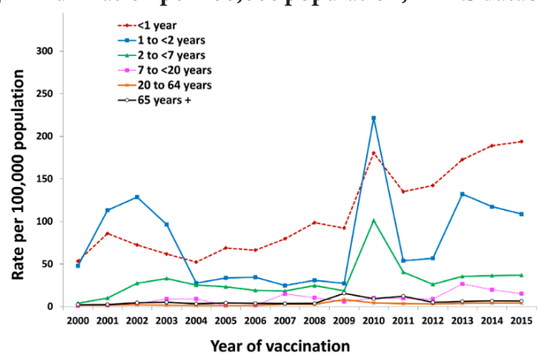
The interesting trends in this line chart (aside from the TIV fiasco and the dotted pink line for the pandemic flu adverse reaction reports in 2010) are the following.

The DTPa-containing vaccines line drops off once the oral polio vaccine (OPV) was replaced with the inactivated polio vaccine (IPV) in 2005. The blue line representing MMR vaccine was fairly constant as the second most reported vaccine until it began rising in 2013. The seasonal influenza vaccine (grey dotted line) has intermittently traded off first place with MMR. Hib-MenC (red line) and MMRV (dotted line) came into use in late 2013 and hold third and fourth place respectively now.

The final Figure in the Australian report is of reporting rates for all age groups. It is very easy to see that rates for less than 1 year olds are highest of all age groups and climbing.

Figure 3: Reporting rates of adverse events following immunization per 100,000 population, ADRS database, 2000 to 2015, by age group and year of vaccination

Of particular interest is the note on syncope in relation to the "enhanced HPV surveillance program". This is a reference to the increase in the pink line for 7 to 20 year olds reporting rates. As we pointed out, in Canada syncope is attributed to "vaccination anxiety" rather than to the HPV vaccine. Syncope is **defined medically** as follows: "Syncope is a sudden, brief loss of consciousness (LOC) with loss of postural tone followed by spontaneous revival. The patient is motionless and limp and usually has cool extremities, a weak pulse, and shallow breathing. Sometimes brief involuntary muscle jerks occur, resembling a seizure."



* Associated with administration of bioCSL Fluvax 2010 TIV and associated stimulated reporting.
** The peak in syncope coincided with the enhanced HPV surveillance program in which there was stimulated reporting of syncope for the first 6 months of 2013.

The next data is given in Table 1, which is the suspected vaccine table for 2015 records organized by age group. We reproduce only the first two portions of the table for children. As can be seen, specific information on doses and two year reporting rates comparisons is presented for pre-school age children less than 7 years old. All of the other age groups only list the number of reports for each vaccine type. This again acknowledges that the Australian Department of Health is particularly concerned with adverse events in the youngest age children who receive the most vaccines.

Table 1: Vaccine types listed as 'suspected' in records of adverse events following immunization by age groups (<7, 7–17, 18–64 and ≥65 years), ADRS database, 2015

Vaccines*	AEFI records† (n)	Vaccine Doses	Reporting rate per 100,000 doses§ (95% CI)	
			2015	2014
<7 years			**Rate (95% Confidence Interval)**	
DTPa-containing vaccines	946	1171740	80.7 (75.7–86.0)	76.5 (71.6–81.6)
Hexavalent (DTPa-IPV-HepB-Hib)	505	862264	58.6 (53.6–63.9)	53.2 (48.5–58.3)
DTPa-IPV	441	309476	142.5 (129.5–156.4)	143.2 (130.3–157.4)
Pneumococcal conjugate -13PCV	479	874250	54.8 (50.0–59.9)	51.1 (46.6–56.0)
Rotavirus vaccine	465	713714	65.2 (59.4–71.4)	61.6 (56.2–67.7)
Measles-mumps-rubella (MMR)	443	575154	77.0 (70.0–84.5)	80.7 (73.8–88.3)
Hib-MenC	199	307737	64.7 (56.0–74.3)	61.0 (52.7–70.6)
Measles-mumps-rubella-varicella (MMRV)	101	303134	33.3 (27.1–40.5)	45.8 (38.8–54.1)
Seasonal influenza	51	79120	64.5 (48.0–84.8)	–
Meningococcal B	40	18995	210.6 (150.4–286.8)	–
Varicella	7	9187	76.2 (30.6–157.0)	94.9 (52.6–171.4)
Meningococcal C conjugate	7	4996	140.1 (56.3–288.7)	124.1 (72.1–213.7)
Haemophilus influenzae type b	5	8051	62.1 (20.2–144.9)	38.6 (16.1–92.8)
Total (<7 years)	**1497**	**4,066,078**	**36.8 (35.0-38.7)**	**37.1 (35.3–39.0)**
7–17 years				
HPV	359	n/a	–	–
dTpa	234	n/a	–	–
Varicella	105	n/a	–	–
Seasonal influenza	48	n/a	–	–
Meningococcal B	9	n/a		
Hepatitis B	7	n/a	–	–
Total (7–17 years)	**553**	**n/a**	**–**	**–**

Note this table is organized by the number of records so one can quickly ascertain the most reported vaccines. The comparable Canadian Table 5 on page 11 here has no organizational structure we can discern. Also of interest in this table is the confidence intervals are given for the reporting rates. Because these are statistical estimates of 95% confidence, presenting the confidence interval shows how much the actual reporting rate may vary from the number presented. Also of import is that the vaccine doses are for doses administered. In other words, this data is collected for this age group so reporting rates are more reliable than doses distributed data would give.

Also note that HPV vaccine has the largest number of reports for the 7 to 17 year old age group, followed by the dTpa booster and the Varicella vaccine.

The next table we examine in the Australian report looks at suspected vaccines again, but breaks the reports down into different categories including **both number and percent of Serious Adverse Events and age groups** of less than 7 years old and greater than 7 years old.

The vaccines with the very large percent of reactions in the under 7 age group (circled in red here) are the

Table 3: Vaccine types listed as 'suspected' in records of adverse events following immunisation (AEFI), ADRS database, 2015

Suspected vaccine type	AEFI records		One suspected vaccine only†		'Serious' §		Age group|| <7 years		Age group|| ≥7 years	
	N	(%)	n	(%)¶	n	(%)¶	n	(%)¶	n	(%)¶
Influenza	599	(20.5)	516	(86.1)	112	(18.7)	51	(8.5)	525	(87.6)
DTPa-IPV-HepB-Hib	513	(17.5)	34	(6.6)	143	(27.9)	505	(98.4)	5	(1.0)
13vPCV	484	(16.6)	16	(3.3)	139	(28.7)	479	(99.0)	3	(0.6)
MMR	481	(16.5)	80	(16.6)	64	(13.3)	443	(92.1)	32	(6.7)
Rotavirus	469	(16.0)	43	(9.2)	141	(30.1)	465	(99.1)	0	(0.0)
DTPa-IPV	453	(15.5)	244	(53.9)	37	(8.2)	441	(97.4)	8	(1.8)
HPV	374	(12.8)	147	(39.3)	32	(8.6)	7	(1.9)	364	(97.3)
dTpa	358	(12.2)	161	(45.0)	27	(7.5)	10	(2.8)	344	(96.1)
Hib-MenC	202	(6.9)	13	(6.4)	45	(22.3)	199	(98.5)	2	(1.0)
23vPPV	184	(6.3)	126	(62.7)	14	(7.6)	14	(3.8)	168	(96.2)
Varicella	123	(4.2)	29	(23.6)	8	(6.5)	7	(5.7)	115	(93.5)
MMRV	108	(3.7)	85	(78.7)	26	(24.1)	101	(93.5)	6	(5.6)
Meningococcal B	60	(2.1)	52	(86.7)	9	(15.0)	40	(66.7)	20	(33.3)
Hepatitis B	56	(1.9)	29	(51.8)	5	(8.9)	13	(23.2)	39	(69.6)
Hepatitis A	28	(1.0)	6	(21.4)	2	(7.1)	13	(46.4)	15	(53.6)
BCG	23	(0.8)	18	(78.3)	4	(17.4)	21	(91.3)	1	(4.3)
dT	22	(0.8)	15	(68.2)	1	(4.5)	0	(0.0)	22	(100.0)
Typhoid	18	(0.6)	6	(33.3)	2	(11.1)	5	(27.8)	13	(72.2)
Hepatitis A-Typhoid	13	(0.4)	7	(53.8)	2	(15.4)	0	(0.0)	13	(100.0)
MenCCV	11	(0.4)	3	(27.3)	1	(9.1)	7	(63.6)	4	(36.4)
Q fever	11	(0.4)	10	(90.9)	0	(0.0)	0	(0.0)	11	(100.0)
Zoster	10	(0.3)	10	(100.0)	1	(10.0)	0	(0.0)	8	(80.0)
Rabies	7	(0.2)	4	(57.1)	2	(28.6)	1	(14.3)	6	(85.7)
Hib	7	(0.2)	1	(14.3)	1	(14.3)	5	(71.4)	2	(28.6)
Hepatitis A + B	7	(0.2)	3	(42.9)	0	(0.0)	0	(0.0)	7	(100.0)
Yellow fever	6	(0.2)	3	(50.0)	0	(0.0)	1	(16.7)	5	(83.3)
Japanese encephalitis	3	(0.1)	1	(33.3)	1	(33.3)	2	(66.7)	1	(33.3)
Tetanus	3	(0.1)	3	(100.0)	0	(0.0)	0	(0.0)	3	(100.0)
Cholera	1	(0.0)	1	(100.0)	0	(0.0)	0	(0.0)	1	(100.0)
Total**	**2924**	**(100.0)**	**1678**	**(57.4)**	**442**	**(15.1)**	**1497**	**(51.2)**	**1377**	**(47.1)**

vaccines used on the youngest babies and toddlers. Almost all of the Serious Adverse Events recorded for these vaccines will have been experienced by these small children.

The above Table shows that Australia has recorded almost double the rate of serious adverse events at 15% compared to Canada, which reported only 8% of all AEFI as being serious.

As to total number of AEFI reports, Australia recorded 2924 AEFI reports in 2015. Canada recorded fewer than Australia that year with only 2845 reports. Australia's population is 30% less than Canada's and they have fewer vaccines in their National Immunization Program than Canada, yet they record more AEFI reports.

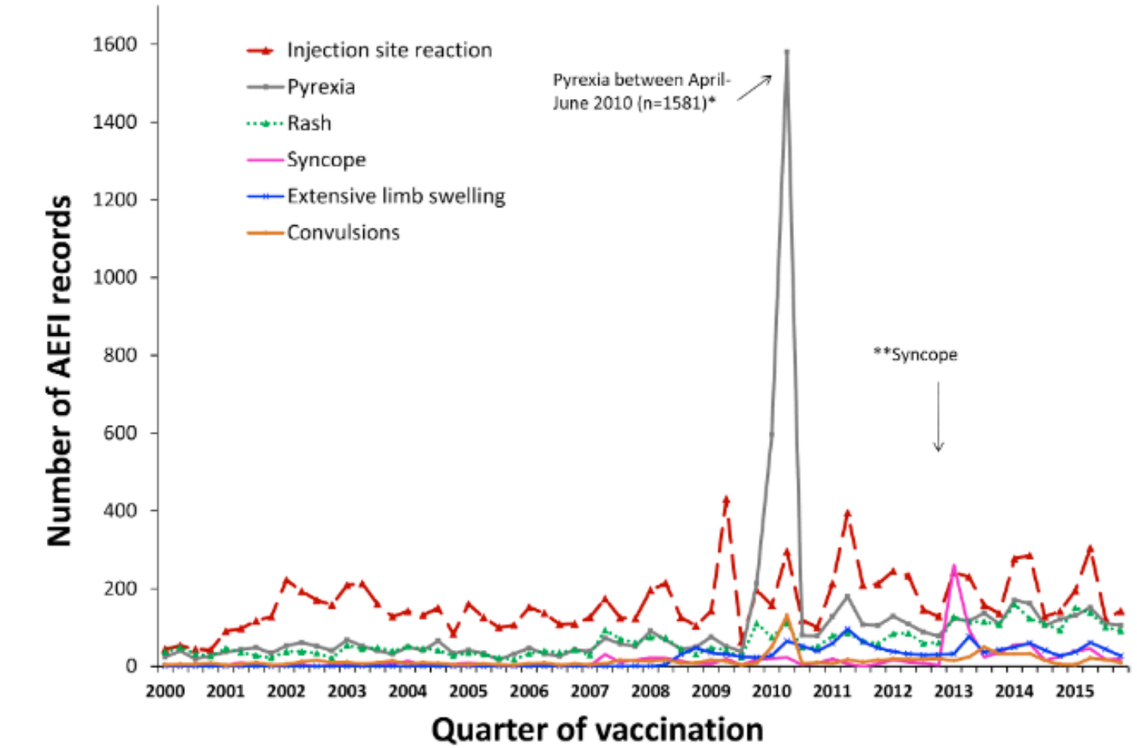
This verifies our concerns that Canada is seriously underreporting adverse events compared to other countries with similar passive surveillance systems.

The final table in the Australian Report is Table 4 reproduced on the following page. It lists the reported adverse event by name, number of reports received, whether these were serious by number and percent and by the under 7 and 7 or older age groups. And they are all listed in order of frequency.

Instead of lumping all the events into categories/sub categories as the Canadian report does in Table 2 and Figures 3 & 4, this report lists the events by the MedDRA preferred terms. CAEFISS could do the same as it has this information as they explicitly state: "*reported AEFIs and medical history information are coded using the International Medical Dictionary for Regulatory Activities (MedDRA, version 17).*" Yet CAEFISS has chosen to lump adverse events into categories and also not report the Serious Event numbers or Age group data.

The last figure (below) in the Australian report shows selected adverse events. A more diverse chart would be of greater use, especially one that showed the less frequent, but more serious events. It does however once again note the syncope issue in 2013.

Figure 4: Selected frequently reported adverse events following immunisation, ADRS database, 2000 to 2015, by quarter of vaccination



All in all, the 2015 Australian adverse events report is far superior to the CAEFISS Summary Report. The data is more complete, relevant and presented in more useful formats, especially for parents who may be making vaccine decisions. That CAEFISS obscures or simply does not publish information on Serious Adverse Events for children is unforgivable! Health Canada and the Public Health Agency of Canada (PHAC) could do much better.

Table 4: Selected reported adverse events and reactions of interest* classified by MedDRA Preferred Terms in records of adverse events following immunisation (AEFI), ADRS database, 2015[¥]

MedDRA Preferred Terms (Adverse events)	AEFI records	Only reaction reported[†]		'Serious'		Age group[‡] <7 years		Age group[‡] ≥7 years	
	N	n	(%)‖	n	(%)‖	n	(%)‖	N	(%)‖
Injection site reaction**	764	361	(47.3)	41	(5.4)	394	(51.6)	362	(47.4)
Pyrexia	497	34	(6.8)	77	(15.5)	331	(66.6)	158	(31.8)
Rash***	481	189	(39.3)	58	(12.1)	330	(68.6)	144	(29.9)
Vomiting	225	27	(12.0)	37	(16.4)	138	(61.3)	85	(37.8)
Headache	196	6	(3.1)	20	(10.2)	13	(6.6)	180	(91.8)
Extensive limb swelling	169	95	(56.2)	10	(5.9)	103	(60.9)	66	(39.1)
Diarrhoea	146	24	(16.4)	32	(21.9)	113	(77.4)	31	(21.2)
Pain	139	19	(13.7)	12	(8.6)	24	(17.3)	113	(81.3)
Urticaria	138	64	(46.4)	12	(8.7)	87	(63.0)	51	(37.0)
Syncope	122	86	(70.5)	22	(18.0)	24	(19.7)	95	(77.9)
Nausea	116	2	(1.7)	10	(8.6)	8	(6.9)	104	(89.7)
Irritability	104	2	(1.9)	19	(18.3)	103	(99.0)	0	(0.0)
Lethargy	100	0	(0.0)	12	(12.0)	48	(48.0)	49	(49.0)
Dizziness	95	4	(4.2)	9	(9.5)	3	(3.2)	86	(90.5)
Pruritus	80	2	(2.5)	6	(7.5)	20	(25.0)	59	(73.8)
Malaise	77	1	(1.3)	5	(6.5)	8	(10.4)	66	(85.7)
Erythema	76	10	(13.2)	9	(11.8)	40	(52.6)	35	(46.1)
Myalgia	55	6	(10.9)	0	(0.0)	3	(5.5)	50	(90.9)
Hypotonic-hyporesponsive episode	55	42	(76.4)	22	(40.0)	55	(100.0)	0	(0.0)
Abdominal pain	54	3	(5.6)	9	(16.7)	22	(40.7)	31	(57.4)
Paraesthesia	53	3	(5.7)	5	(9.4)	0	(0.0)	51	(96.2)
Convulsions****	52	31	(59.6)	39	(75.0)	51	(98.1)	0	(0.0)
Chills	51	1	(2.0)	9	(17.6)	5	(9.8)	46	(90.2)
Presyncope	44	29	(65.9)	5	(11.4)	8	(18.2)	33	(75.0)
Decreased appetite	39	0	(0.0)	6	(15.4)	26	(66.7)	13	(33.3)
Cough	38	1	(2.6)	5	(13.2)	14	(36.8)	24	(63.2)
Dyspnoea	37	0	(0.0)	9	(24.3)	5	(13.5)	32	(86.5)
Fatigue	36	0	(0.0)	2	(5.6)	2	(5.6)	34	(94.4)
Arthralgia	35	1	(2.9)	0	(0.0)	4	(11.4)	29	(82.9)
Pallor	30	2	(6.7)	6	(20.0)	16	(53.3)	13	(43.3)
Intussception	25	24	(96.0)	15	(60.0)	24	(96.0)	0	(0.0)
Somnolence	23	1	(4.3)	1	(4.3)	13	(56.5)	10	(43.5)
Anaphylactic reaction	22	21	(95.5)	10	(45.5)	3	(13.6)	16	(72.7)
Hyperhidrosis	21	0	(0.0)	3	(14.3)	2	(9.5)	18	(85.7)
Hypoaesthesia	20	2	(10.0)	4	(20.0)	0	(0.0)	20	(100.0)
Haematochezia	18	9	(50.0)	9	(50.0)	18	(100.0)	0	(0.0)
Chest discomfort	18	0	(0.0)	5	(27.8)	0	(0.0)	18	(100.0)
Tachycardia	16	1	(6.3)	5	(31.3)	7	(43.8)	8	(50.0)
Oropharyngeal pain	14	0	(0.0)	3	(21.4)	0	(0.0)	14	(100.0)
Rhinorrhoea	13	1	(7.7)	0	(0.0)	7	(53.8)	5	(38.5)
Tremor	7	1	(14.3)	0	(0.0)	0	(0.0)	7	(100.0)
Guillain-Barre Syndrome	6	6	(100.0)	5	(83.3)	1	(16.7)	5	(83.3)
Lymphadenitis	5	2	(40.0)	0	(0.0)	2	(40.0)	3	(60.0)

Part 5: Reporting Rates—What does it all mean?

Real Events versus Reported Events

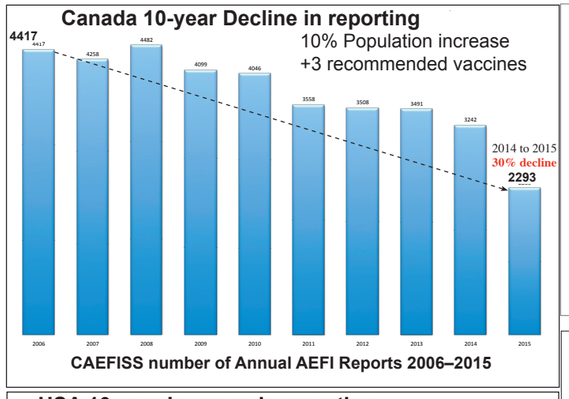
In the past, public health agencies in the USA, Canada and elsewhere have suggested that 10% of adverse events following vaccination are being reported. No such estimate of real reporting rates is found in this current report or in other recent Canadian reports, although underreporting is (as usual) mentioned.

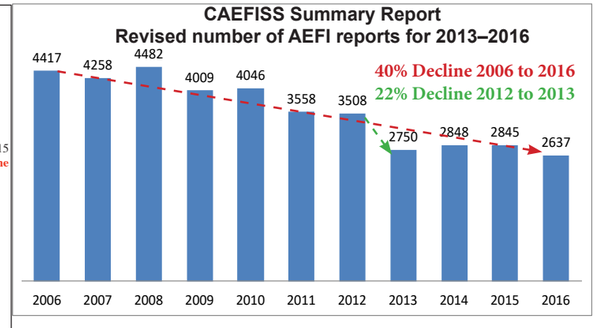
In fact, a **2011 American report**—funded by the Department of Health and Human Services, which is the American equivalent of Health Canada—stated (on page 6): *"Likewise, **fewer than 1% of vaccine adverse events are reported*** [to VAERS]. *Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed."* The mandate of the group who wrote this report was to develop software for use by doctors and other health professionals to increase the extremely low AEFI reporting rates. Although the software was developed, funding to implement the first trial of its use was cut and the entire project was shelved. You can read the details in the report linked above.

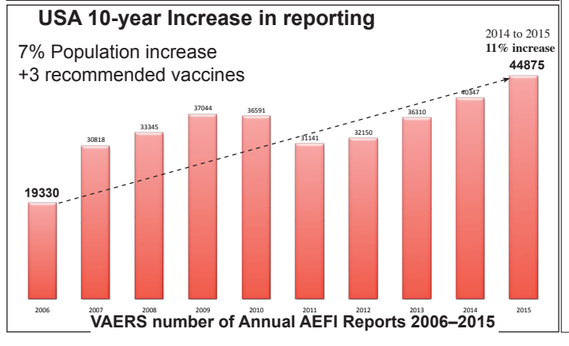
A **2018 Vaccine Safety Report** from the European Forum for Vaccine Vigilance (EFVV) states: "*Adverse events will require medical care and have a cost attached. They are generally accepted to be underreported by 1 in one-hundred (only 1% of events are reported). More recent research suggests that is incorrect and that the actual underreporting is more like 1 in 200 or only 0.5 % reported, leaving 99.5% unreported.*"

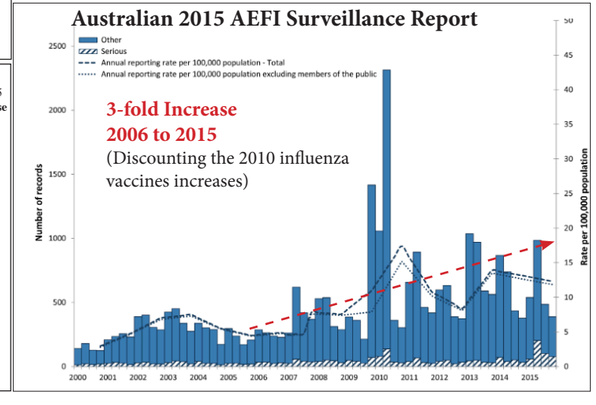
Underreporting in Canada

As detailed in ***Vaccine Safety Report 2***, the number of reports to the American VAERS system has increased while the number to Canadian CAEFISS has declined. The charts from that report are reproduced below on the left. A chart of the **revised report numbers** per the CAEFISS Summary Report for 2013-2016 is shown on the top right. Both CAEFISS charts show declines in AEFI report numbers. Both the USA and the Australian charts show increases in report numbers commensurate with increases in vaccine schedules and with population growth.









The new CAEFISS chart has one more anomaly that begs comment. Notice the 22% drop in AEFI reports from 2012 to 2013. Whenever new vaccines are introduced or new portions of the population are recommended to use existing vaccines, it is expected by public health officials that reporting rates will increase.

There were four major changes to **vaccine recommendations in November of 2012** that should have produced an increase in 2013 AEFI report numbers, especially since the vaccines involved have proven to be highly reactogenic. These changes included (but were not limited to) the following:

1) Introduction of the **hexavalent DTaP vaccine** (InfanrixHexa®) that contained HepB as well as IPV and Hib, 3 doses for use in children <1 year old (now in use in 5 jurisdictions).
2) Introduction of **Pneumococcal 13-valent vaccine** to replace 7-valent, 3 doses in children <1 year old.
3) Introduction of the **Shingles vaccine** (Zostavax®) recommended for use in adults >50 years old.
4) Tdap booster recommended for use in pregnant woman and all adults in contact with infants (the failed "cocooning" program to control whooping cough in infants).

No explanation is offered as to why there is 22% **decline** in AEFI reports in 2013, rather than an increase.

Choosing the CAEFISS Reporting Rate

If the reporting rate to VAERS in the USA represents "fewer than 1% of vaccine adverse events", then assuming **a 1% reporting rate in Canada is very generous indeed**. However, for ease of calculations we will use that 1% rate in the following section where we attempt to ascertain how many adverse events are actually occurring, especially serious events for vaccinated children. These estimates of events will be low for the reasons mentioned.

While all of the AEFI Surveillance reports we have read make a point of saying that reporting rates of adverse events are not a proxy for the actual occurrence of adverse events, in a strange twist most reports do make the claim that the low reporting rates show how safe vaccines are. The CAEFISS Summary Report conclusion is a case in point:

> ***"Conclusion***
> *Canada has a comprehensive vaccine surveillance system that revealed an average AEFI rate of 8.9/100,000 population. There were no unexpected vaccine safety issues identified or increases in frequency or severity of expected adverse events. The majority of reported AEFIs were expected and mild in nature and there were no unexpected or increases in serious adverse events. Vaccines marketed in Canada continue to have an excellent safety profile."*

What a 1% reporting rate means is that report numbers received by CAEFISS must be multiplied by 100 to reflect the number of **actual** adverse events that these reports represent.

One cannot use a number that represents a tiny portion (less than 1%) of events actually occurring, pretend it represents all such events and then conclude that out of many millions of vaccine doses only that tiny fraction of adverse events occurred. This is exactly what the *CAEFISS Summary Report* does when it concludes that vaccines "have an excellent safety profile".

This is neither mathematically correct, nor logically meaningful. Only if 100% of AEFIs were reported and recorded could such a safety attribution possibly be made. We repeat: Using the exceedingly low reported number of adverse events in rate calculations that use the real number of vaccines distributed creates a seriously false impression of the actual number of adverse events occurring and thus the purported safety of vaccines.

Another way to address the mathematically contorted reporting rate statistic would be to compare the number of reported adverse events to 1% of the vaccine doses distributed, rather than comparing to all the doses.

For example, if 2000 AEFIs are reported one year and approximately 20 million vaccines are distributed that year, then 1% of those doses would be 200,000 doses. And so 2000 reported adverse events would give a REAL event rate of 1000 AEFI per 100,000 vaccine doses or 1 Adverse Events per every 100 vaccine doses distributed. This is very different from 2000 AEFI per 20 million doses distributed,

It should be mentioned that Canada is not alone in this disinformation campaign. All internationally established pharmacovigilance schemes we have looked at use the low reported AEFI numbers per actual number of vaccine doses as a proxy for actual adverse events occurring to assure us that vaccines are safe.

Rare Reporting Not Rare Events?

The only thing that the currently contrived reporting rates are concretely telling the public is that fewer and fewer adverse events are being reported over time in Canada. **This does NOT mean that fewer AEFIs are actually occurring.** Diminished reporting likely reflects an ideology on the part of medical professionals that vaccines are

safe, rather than any attempt to collect and analyze empirical data that would prove otherwise.

As **any parent whose child has suffered a serious adverse event** following vaccination knows, neither medical professionals nor public health agencies are likely to credit a vaccine as the cause of or even related to the adverse event. Coincidence, pre-existing medical conditions, unexplained reasons or parental choices or negligence are preferred explanations.

Further, there is no acknowledgement in the medical industry as a whole that what are deemed "non-serious" adverse events play a role **over time** in vaccine injury. Thus the decline in reporting of these events is of concern. Family physician, Dr. Richard Moskowitz, in his recent book ***Vaccines—A Reappraisal,*** establishes that vaccinations cause inflammation in many children and that this inflammation **over time** has lead to the epidemic of chronic diseases (many of which involve damaged immune systems/brain function) that we now see in vaccinated populations. The significance of even common, mild reactions to vaccines is thus brought into focus as the signal that inflammation has occurred and will continue to occur as more vaccines are administered under childhood and adult vaccine schedules. Dr. Moskowitz is not alone in these conclusions. Many other medical doctors and independent researchers affirm this. We cite Dr. Moskowitz here as his book is particularly useful for parents facing vaccine decisions, especially when assessing their childrens' responses to vaccines.

Actual Adverse Event Numbers

When assuming a 1% reporting rate and multiplying the total number of passive system reported adverse events (10,673) in the Summary Report (Figure 1) by 100, we see that it is likely that at a minimum of **over one million** (1,067,300) **adverse events occurred in this 4-year period**. As the report Abstract states, *"The majority of reports (92%) were non-serious events, involving vaccination site reactions, rash and allergic events."* The list of adverse events deemed "non-serious" is of course far more extensive than this, as shown in Table 2 in the report. These are the very events that indicate inflammation, which Dr. Moskowitz describes as signals for future harm.

Serious reports represent 8% of the over one million actual events. However SAEs are a special case since they include both active and passive reporting in Canada. Therefore we cannot apply the 1% reporting rate across the board to serious adverse events. See the discussion below for details on serious adverse event rates.

Actual AEFI Events per 100,000 Doses of Vaccines

Since what the public really wants to know is how many adverse events actually occur for doses distributed, not how many adverse events are reported by health professionals, let's look at what rates of **actual** AEFI occurrence would look like if the AEFIs that are being reported represent only 1% of AEFIs that are occurring.

Returning to Figure 1 in the report and the accompanying text description, we can use this information to arrive at an answer to our question on how many events are actually occuring per 100,000 doses distributed.

"A total of 11,080 AEFI reports (2,750 AEFI reports in 2013, 2,848 in 2014, 2,845 in 2015 and 2,637 in 2016) from 12 PTs were received by CAEFISS during 2013–2016. Over 80 million vaccine doses were distributed, representing reporting rates of 12.1–14.3 per 100,000 doses distributed…"

Text description: Figure 1

Year	Passive system	Active system	Total number AEFI	Reporting rate per 100,000 doses distributed
2013	2666	84	2750	14.3
2014	2735	113	2848	14.0
2015	2754	91	2845	13.2
2016	2518	119	2637	12.1

Step 1: Annual Number of Vaccine Doses

In order to calculate annual rates for actual events per 100,000 vaccine doses, we first must extrapolate the number of doses distributed each year from the data given for the number of reports and the reporting rate per 100,000 doses. Extrapolation results in the following number of vaccine doses distributed for the 4 years given in the text description above:

2013: 19.2 million doses 2014: 20.3 million doses 2015: 21.6 million doses 2016: 21.8 million doses

The total of all doses distributed in the four years is 82.9 million doses. This correlates with the non-transparent statement in the report of "more than 80 million doses" distributed.

We also note that in the 4 years represented, vaccine doses distributed have steadily increased. The increase over the 4 years is 13.5% (19.2M to 21.8M). This increase is very significant when considered against the backdrop of the 4% decline in the number of AEFIs reported over the same 4 years.

A caution is necessary before we proceed. We are using the CAEFFIS numbers as presented in the report to arrive at our answers. But there are further problems with their numbers (aside from the differences from numbers previously published).

First, only 12 provinces/territories are represented in the report numbers. In one case, the report mentions removing the estimated number of reports for the non-reporting (unnamed) jurisdiction to re-calculate reporting rates. The report never mentions adjusting dose data for the missing jurisdiction however. It is unclear if that adjustment was made. This appears unlikely for two reasons:

The report makes clear that the numbers of doses distributed were received from manufacturers through an "agreement", so apparently the public health arm of our government does not track distribution numbers even though it should since vaccines are purchased from manufacturers under federal government **contracts** which list specific jurisdictions for distribution. (As an aside, if one searches the **government procurement site** for the word ***vaccine*** a list of all vaccine related goods and services with many sorting filters is found. Services include literature reviews and vaccine studies that the government purchases from various private bidders.)

If the total doses number was not adjusted then the number of doses distributed in only 12 provinces would be smaller than those used in the reporting rate calculations in the Figure 1 chart above. Thus the reporting rates given in the chart would be slightly higher than shown.

Second, doses distributed is a larger number than the doses administered (due to unused, expired and **spoiled vaccines**). Using the larger number of doses distributed for calculations of reporting rate further increases the rate.

Due to both of these considerations, our calculated numbers for actual AEFIs are likely to be low.

Step 2: Annual Number of Actual Adverse Events per 100,000 Vaccine Doses

Having extracted the number of doses distributed for each year, we can calculate how an actual AEFI rate would look if the reports represent 1% of all AEFIs that are occurring. Since the 1% report rate applies to passive reporting systems, we will use the number of passive systems reports from Figure 1 for our calculations. Of note is that active reports account for only a small percent of the total AEFI reports (3.67%, with a range of 3–4.5%).

Example 2013 calculations

Using the 1% reporting rate method:

2666 passive system reports are 1% of 266,600 actual events. If 266,600 actual adverse events occurred for the 19.2 million vaccine doses this equals **1,389 adverse events per 100,000 doses distribute**d.

Using 1% of doses distributed method:

192,000 doses are 1% of 19.2 million doses and result in 2666 passive system AEFI reports,
Therefore 1,389 actual adverse events occurred for each 100,000 doses distributed.

Following either calculation method for all 4 years results in the following **AEFI actual occurrence rates**

Actual Adverse Event Rate	Reporting Rate
2013: 1389 AEFI events /100,000 vaccine doses	**of which 14.3 were reported**
2014: 1347 AEFI events/100,000 vaccine doses	**of which 14 were reported**
2015: 1275 AEFI events/100,000 vaccine doses	**of which 13.2 were reported**
2016: 1155 AEFI events/100,000 vaccine doses	**of which 12.1 were reported**

For the entire 4-year period 1,067,300 AEFI occurred for 82.9 million doses distributed, therefore:

On average 1290 actual AEFI events occurred per 100,000 vaccine doses distributed.

This can also be stated as **129 actual AEFI per 10,000 doses** distributed or reduced further to **13 actual AEFI per 1,000 doses distributed**. Regardless of which rate is used, it paints a very different picture of what is occurring for real children and adults who are being vaccinated in Canada.

Actual SAE Events per 100,000 Doses of Vaccines

Calculatingly actual SAEs per 100,000 doses of vaccines distributed is not such a simple process, since SAEs are reported by both active and passive systems to the CAEFISS database.

Active Reporting

In 2001, the Canadian Pediatric Society set up the **IMPACT system** (with tax-payer funding) to actively monitor Serious Adverse Events in childrens' hospitals. Currently there are 12 hospitals in eight provinces participating in the program. Three territories and two provinces do not have hospitals in the program. There are **limitations** to the IMPACT program as the Summary Report explains: *"IMPACT uses predetermined AEFI targets (such as seizure), which may limit its ability to identify new adverse reactions to immunizations. In addition, IMPACT focuses on admitted pediatric cases, which means only the most serious cases are detected. Lastly, IMPACT is not comprehensive, as it covers only 90% of Canada's tertiary care pediatric beds and hospital admission."* Note in our calculations we have not added an additional 10% to the report numbers to account for non-IMPACT tertiary care hospitals.

As to which children IMPACT sees, we don't know that all children suffering from serious adverse events following immunization receive proper primary care from a pediatrician/physician or secondary care at a regional or community hospital emergency department. Of those who are not discharged from emergency departments and are admitted as secondary care hospital inpatients, only some will be transferred to tertiary pediatric care beds in IMPACT hospitals. Also some children who are referred to tertiary care IMPACT hospitals will be **referred back** to secondary care hospitals. So this presents a very confusing picture of the population of children suffering serious adverse events and what portion are being actively surveilled for these events.

Active SAE Report Data

Examining the number of Active System reports noted in Figure 1 gives us the following information on SAE's reported by IMPACT to CAEFISS. These are all severe, serious reports for children less than 18 years old and are considered to be a 100% (rather than a 1%) report of events actually occurring.

Active SAE Reports per Figure 1

2013: 84 of 2750 = 3% 2014: 113 of 2848 = 4% 2015: 91 of 2845 = 3.2% 2016: 119 of 2637 = 4.5%

Total Active SAE reports = 407 reports of actual events or an Average of 102 SAE events yearly

Average over 4 years = 3.7% of all AEFI reports

Passive SAE Report Data

Note we cannot perform a calculation for each year as no where in the report are the passive or total SAE report numbers given on an annual basis. However we can calculate the actual number of SAEs represented by the Passive SAE Reports at a 1% reporting rate for all 4 years. The report says there were **892** (or 894) SAE reports.

892 – 407 SAE Active reports recorded = 485 Passive SAE reports

Therefore these 485 passive SAE reports at a 1% reporting rate represent a total of 48,500 actual SAEs.

Actual Serious Adverse Events Occurring

Adding our numbers for active (407) and passive (48,500) events together we arrive at **48,907** serious events. The total of all doses distributed in the four years is **82.9** million doses. So the rate of actual SAEs occurring is 48,907 per 82.9 million doses for the four years in this report.

Calculating the 4-year rate of actual SAE/100,000 doses we arrive at:

550 actual SAE/100,000 doses of which 1.1 were reported

This gives an annual average of 138 actual SAE per 100,000 doses distributed

This can be further reduced to 14 actual SAE per 10,000 doses or

1.4 actual SAE occur per 1000 doses distributed

If one were to be so bold as to consider that the average Canadian child receives **18 doses** of combination and monovalent vaccines by the time they are 18 years old and **36 doses** if they get annual flu shots**, it becomes even more obvious that serious adverse events are not as rare as we have been led to believe.**

Conclusion

Reporting rates do not represent actual rates of adverse events that occur following vaccinations. Over 1 million adverse events following vaccination likely occurred in the 4 years covered by this report. Of those adverse events, almost 50,000 serious adverse events occurred. As always the youngest children who receive the most vaccinations in the shortest time period suffered the most number of serious adverse events.