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

Vaccine Safety Report 7

An analysis of 2017 Adverse Events Data & Databases

Contents

Blue text in the digital version of this report is hyperlinked to references.

Canada has TWO separate surveillance systems, both of which receive reports of Adverse Events

- **CAEFISS**—the Canadian Adverse Events Following Immunization Surveillance System, and
- **CV**—the Canada Vigilance system.

Definition of Terms in Adverse Event Reports

AEFI: Adverse Event 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." Reports can be either non-serious or serious.

SAE: Serious Adverse Events

An SAE is defined as an adverse event that results in one or more of the following:

- Death,
- A Life Threatening event (e.g., cardiac arrest or anaphylactic shock),
- Hospitalization or Extended Hospitalization,
- Disability (e.g., paralysis or blindness),
- Congenital deformity (relates to pregnant mother vaccination resulting in damage to the fetus)

Safety Signals

Safety signals relate to the use of a vaccine in the general population after the vaccine has received license approval based on Random Clinical Trials (RCTs) by the manufacturer of the vaccine. These **pre-market** trials determine the list of adverse events in the product literature. This is why one should always read these monographs.

Post-Market 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 previously reported (NPR) for this vaccine or documented in the product literature.

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Introduction

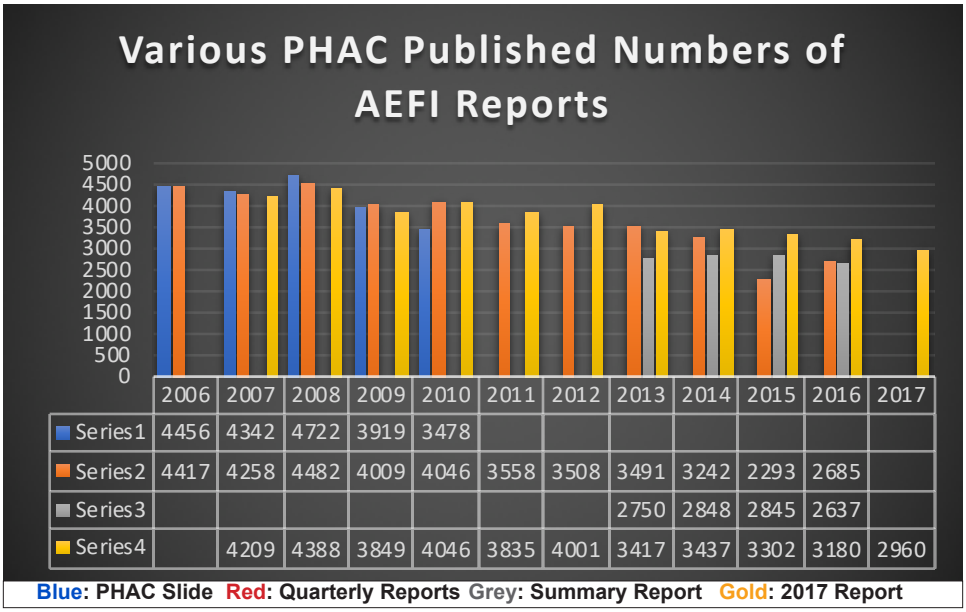
In September of 2018, the Public Health Agency of Canada (PHAC) published a 4-year Summary Report (2013–2016) on adverse events data from **CAEFISS.**

Three months later, in December of 2018, an Annual Report of 2017 CAEFISS data was published by PHAC. The 2017 Report is analyzed in our report that follows.

No Quarterly Reports were published for 2017, so apparently we are seeing an unannounced policy change: 1) to publish only an Annual CAEFISS Report on Adverse Events following vaccination and 2) to publish that report in the questionable format established in the Summary Report, but with even more AEFI information deleted.

But most worrying, once again the new numbers of AEFI reports for previous years are all different than the ones previously published by PHAC.

Why? How? Which numbers to believe?



Blue: PHAC Slide Red: Quarterly Reports Grey: Summary Report Gold: 2017 Report

As seen in the chart, from the report published only 3 months previously to reports published 12 years ago, **all of the total numbers of adverse event reports for each year have changed.** In the early years, published numbers from different PHAC sources are similar, but have diverged since. Note the Summary Report (grey) is a complete outlier with much lower numbers.

Further, the 2017 total number of AEFI reports has fallen below 3,000 **for the first time since 1987** as seen on PHAC Slide (#52). This is disturbing considering the population of Canada increased by 38%, from 26.5 million in 1987 to 36.6 million in 2017. As well, seven recommended (publicly funded) vaccines and numerous booster doses have been added to vaccine schedules. The schedules also affect much larger portions of the population including children, teens, adults, the elderly and pregnant women. Other vaccine have also been developed and marketed since 1987. Yet we see fewer and fewer AEFI reports over the years.

For Canada's second adverse reaction database—**Canada Vigilance (CV)**—vaccine manufacturers and distributors (MAH's) are required under the *Food and Drug Act* to submit all serious adverse event (SAE) reports to the database. However, this database also includes serious and non-serious reports from healthcare professionals and the public as does CAEFISS.

2017 also saw a policy change in report timing for the CV database 'vaccine safety' reports from quarterly reports to biannual reports. The CV database can be searched on-line by the public, although the search functions are not completely accurate. However, we do our best to verify particularly concerning reports.

Like CAEFISS, AEFI report numbers have declined over time on the CV database. In December 2018, Health Canada issued a publication covering annual trends over 10 years of adverse reaction (AR) reports **on the CV database**. This report covers all pharmaceuticals as well as biological products and medical devices. The trend in AR reports is stated as follows: "Since 2008, there has been a continuous increase in AR case reporting to Health Canada from 15,551 cases in 2008 to 64,617 cases in 2017." that's an increase of more than 300%.

Digging into the report however, we found that vaccine adverse event reports (given for 2013–2017 only) are not increasing. In fact, 2017 shows the lowest number of vaccine reports for those 5 years. This confirms our suspicion that unlike adverse reactions to other medical products, vaccine adverse events are not being reported accurately. (See page 20 for more VCC analysis of the Trends report.)

Our Questions

How can the published numbers of AEFI safety surveillance data fluctuate so much if it is truly **empirical** data? Why are there such large declines in AEFI report numbers? Why is so much information being removed from surveillance reports? How can any of this possibly reassure the public about vaccine safety surveillance systems in Canada?

Part 1: Adverse Event Reports 2017—The Simple Story

The vaccine safety reports are statistical studies. They present collected data on reported adverse events following immunization (AEFIs). Statistics are complicated however. As one well-known statistician quipped, "What they reveal is suggestive, but what they conceal is vital."

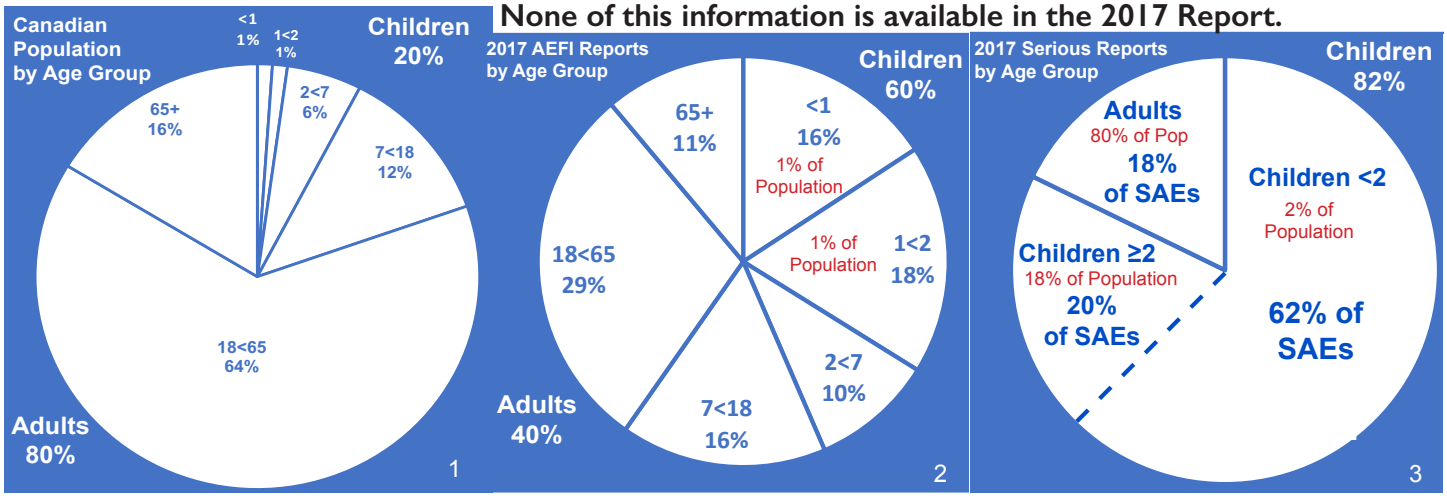
Four sets of data are basic to the understanding of who is being negatively affected by vaccines and why that is so: 1) population by the age groups delineated in the report, 2) AEFI reports for each age group, 3) Serious AEFI reports for each age group and 4) publicly-funded vaccines administered to each age group.

As can be seen from the 3 pie charts, children make up 20% of the population, yet experience 60% of all reported adverse events and 82% of all reported serious adverse events (SAEs) in 2017.

As to why this is the case, it's simple. Vaccination programs target children with many vaccines and uptake of childhood vaccines is high in all provinces.The younger the child, the more vaccines in the schedule. Depending on age group and specific vaccines, 70–95% of all children in Canada are vaccinated to schedule.

For comparison, uptake by adults of the three publicly funded, communicable diseases vaccines (Influenza, Pertussis, Pneumococcal) is 10%–40% depending on the vaccine.

None of this information is available in the 2017 Report.



Canada: Vaccine Doses in Childrens' 2017 Routine Schedules—Prenatal to Age 18

A total of 19 different vaccines are used for Canadian children

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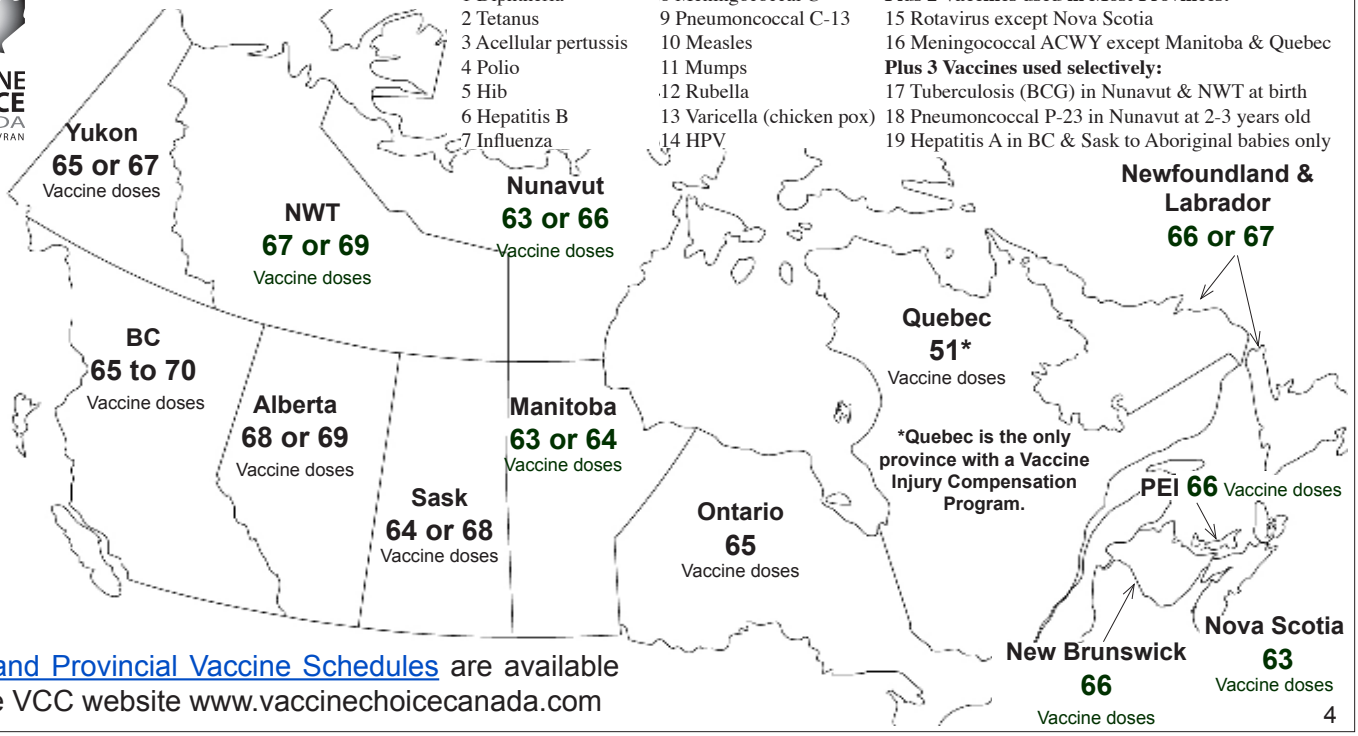
There are 14 vaccines used in All Provinces:
1 Diphtheria
2 Tetanus
3 Acellular pertussis
4 Polio
5 Hib
6 Hepatitis B
7 Influenza
8 Meningococcal C
9 Pneumoncoccal C-13
10 Measles
11 Mumps
12 Rubella
13 Varicella (chicken pox)
14 HPV

Plus 2 Vaccines used in Most Provinces:
15 Rotavirus except Nova Scotia
16 Meningococcal ACWY except Manitoba & Quebec

Plus 3 Vaccines used selectively:
17 Tuberculosis (BCG) in Nunavut & NWT at birth
18 Pneumoncoccal P-23 in Nunavut at 2-3 years old
19 Hepatitis A in BC & Sask to Aboriginal babies only



Map and Provincial Vaccine Schedules are available on the VCC website www.vaccinechoicecanada.com

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Causality: A NOT So Simple Story

For the vaccine industry there is an established story line about whether vaccines actually cause reported adverse events. It is not a simple story. It contains many established assumptions as the basis for developing causality assessment tools. We comment on a few of these assumptions or beliefs below.

Causality assessments were established due to concern that babies and children were suffering adverse events following vaccinations. This concern and the accompanying story line is described well in the introduction to a 2005 paper on the Brighton causality assessment. Selected quotes and our comments follow.

"In 1974, the World Health Organization (WHO) launched its Expanded Programme on Immunization (EPI). Since then the proportion of children immunized against routine vaccine-preventable diseases has increased from 5 percent to around 80 percent during their first year of life, with a corresponding decrease in disease rates."

"Unfortunately, like all medical interventions, no immunization is perfectly safe. With the increase in vaccine coverage in both developed and developing countries, and the reduction in target vaccine-preventable diseases (VPDs), has also come a growing concern for the safety of immunizations. This is due to an increase in the absolute number of adverse events following immunizations (AEFIs) as well as their increased prominence relative to the decline in VPDs."

In other words, more children were being injured by vaccines than were getting ill from the diseases the vaccines target and parents especially became concerned. What to do? The authors continue:

"*For vaccines targeted against diseases where herd immunity exists, individual risk-benefit assessment diverges from that of the society at high vaccine coverages.[5] With many VPDs having become so rare that most parents (and, increasingly, providers) are no longer familiar with their risks and complications, the actual or perceived risk of experiencing any AEFI may outweigh the actual or perceived benefit of immunization to a given individual."*

These two sentences describe the origins (decades ago) of 'vaccine hesitancy' when the actual risk of experiencing an AEFI began to outweigh the actual benefit of vaccination for any individual. They also describe the industry's response: (drum roll) enter herd-immunity theory pitting individual risk against societal risk to justifying 'high vaccine coverages'.

However, the footnote for the first sentence is a paper (Fine & Clarkson, 1986) titled, Individual versus public priorities in the determination of optimal vaccination policies. Here is the abstract of the paper:

"There is a tendency for governments to decide whether or not to offer routine vaccination on the basis of arguments of financial cost, whereas individuals decide whether or not to accept vaccination on the basis of their perception of the risks involved. ***Furthermore, some vaccines impart, or appear to impart, a degree of indirect protection to nonvaccinated individuals in the community.*** *For both of these reasons, public motives concerning vaccination differ from those of the individual. The quantitative implications of these differences are explored in this paper.* ***It is found that, under a broad range of conditions, rational informed individuals would "choose" a lower vaccine uptake*** *than would the community if it acted as a whole. The result is applied to the pertussis situation in England over the past 30 years and provides a measure of a public's changing perception of the risks associated with that vaccine."* [emphasis ours]

While refreshing to see a reference to 'rational, informed individuals' choosing fewer vaccines rather than references to "anti-vaxxers" and other pejoratives we see today, nevertheless, vaccines are said to impart, or "*appear to impart*" indirect protection to others. Yet we know today that pertussis vaccines do not confer 'herd immunity' because they are not designed to stop transfer of the disease, only to mitigate symptoms.

Further, the whole cell DPT vaccine, in use when this paper were written, was removed from the market due to its high injury rate. It was a huge, very public, vaccine controversy and the impetus for the establishment in 1986 of vaccine injury compensation and removal of liability for vaccine injury from manufacturers in the USA and establishment of CAEFISS as a separate database in Canada. A curious paper to select to support a statement that includes herd immunity theory. It does support the establishment of individual vs. policy-maker views on the subject of vaccine risk, even if policy-makers are not 'the community' or 'society'. (They only wish they were.)

Now, what about the statement that parents and providers are no longer familiar with the risks and complications of vaccine preventable diseases (VPDs). We agree in that we hear much of how rare adverse event responses to vaccines are, but very little about how rare the risks and complications of VPDs are.

The connection, on an individual level, between response to a disease and response to a vaccine for that

disease is brought to light by Dr. Suzanne Humphries in her highly recommended video series Vaccines: Honesty vs. Policy. In Part 5: One Size Does Not Fit All, she discusses individual variation and the work of four researchers on this subject, including Dr. Gregory Poland. What their work tells us is that individual variation in genetic factors and immune mechanisms affect the response to a disease **and** the response to the vaccine against that disease as well. In other words, Humphries explains, *"Healthy children who respond well to vaccines are the ones who would have had a good prognosis with the disease and recovered uneventfully. So parents are vaccinating their healthy children against diseases they would have easily recovered from with no complications. Children who do not respond well to the vaccine are the ones who would have the worst time with the disease."*

And we add, these latter susceptible children may have less risk of acquiring a disease to which they respond badly as VPD rates lower, but the high vaccine coverage rates **increase their risk of injury by vaccines** carrying that disease virus or bacteria.

Note this only concerns the effect of the **active ingredients** (disease viruses or bacteria) in vaccines, not all the other ingredients that cause adverse reactions like adjuvants or fetal cell lines or antibiotics or polysorbates and so forth.

Next, we ask the common question: if VPDs have declined so much why are we continuing to vaccinate against them? In the next few sentences is their answer to that question and it may surprise you:

"However, decreases in immunizations have been shown to lead to higher incidence of VPDs in individuals or to community-wide outbreaks. Additionally, few VPDs are eradicable, and even for those that are, stopping immunizations may be unwise in an era of bioterrorism. Therefore, most immunizations will have to continue indefinitely, with their associated risks and the need to maintain the highest safety standards possible."

Bioterrorism? We must continue vaccinating indefinitely because of bioterrorism? To our knowledge no VPD bioterrorism has occurred anywhere in the world to this day. However we leave this for the reader to contemplate.

As to higher incidence of VPDs, the revelation by Dr. Humphries above does not suggest that most children would be put at higher risk if VPDs increased. We also know that largely benign childhood diseases like measles, mumps, chicken pox and even influenza prime the immune system of unvaccinated children at an appropriate age naturally and even confer benefits to future, long term health. Juxtaposed to this information is the knowledge that vaccines have shifted disease burden to older age groups (where diseases may be less well tolerated) and also led to even more virulent forms of VPDs for which there is no vaccine protection. In this category are para pertussis and acute flaccid paralysis, not to mention new strains of hepatitis, pneumococcal and meningococcal bacterial that put us on a vaccine production treadmill. Finally, the ultimate question is why ending smallpox vaccinations did not lead to increased incidence of that disease. In empirical science, one exception like this destroys the hypothesis and a new hypothesis must be considered.

As to outbreaks, yes, we see outbreaks. But when public health officials define an 'outbreak' as **one or more cases** of a disease that is surely to be expected. Even when an outbreak of some 100 cases of a disease occurs in a population of over 320 million people (as in the 2015 Disneyland measles outbreak), this is hardly cause for alarm. Especially considering that some vaccinated individuals are always among the individuals that succumb to the disease along with unvaccinated individuals. Only 45% of the Disneyland cases were documented as unvaccinated.

Nor is it ever mentioned that natural measles and chickenpox infection confers near life-long immunity, unlike waning vaccine acquired 'immunity'. Likewise, many of the VPDs vaccinated against really are benign childhood illnesses or easily controlled, especially in developed countries with well-nourished children who drink clean water and live with modern sewage systems and have access to good health care. This is a clue as to how we could better help under-developed nations fight disease instead of the 'vaccine cure' and its attendant injuries and illnesses.

Finally the statement quoted above about "the need to maintain the highest safety standards possible" leads us to point out high safety standards must be **established** before they can be **maintained**.

Nevertheless, the statement leads into their discussion of how excellent manufacturer's pre-licensure safety trials are (never mind design bias or no placebos) and how AEFI surveillance systems are their post-market 'safety' solution. Of course, they must be sure that all those AEFIs are truly related to vaccines, therefore assessment criteria were developed. The Brighton criteria were the tool used until recently to assess causality of adverse events. See Part 4 for causality assessments using the Brighton Criteria and a discussion of the revised WHO criteria in use today.

Part 1: CAEFISS 2017 Vaccine Safety Report—Analysis
The Canadian Adverse Events Following Immunization Surveillance System

2017 AEFI Reports

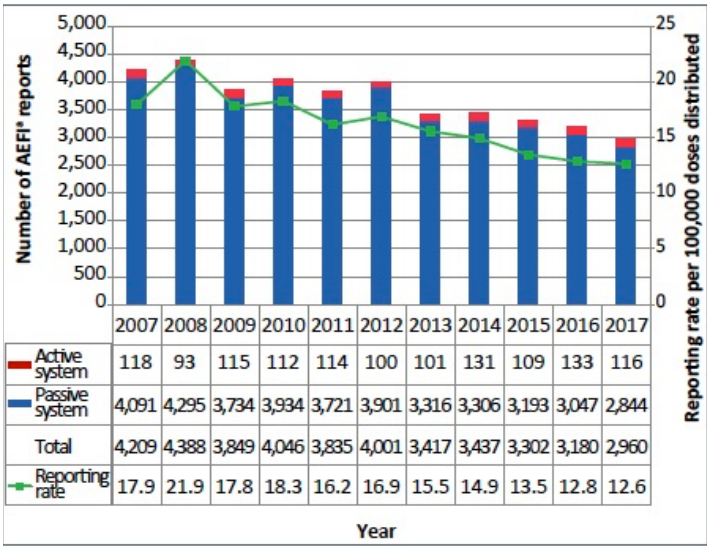
On Dec. 6, 2018, PHAC published an annual report titled *Vaccine safety surveillance in Canada: Reports to CAEFISS, 2017*. We will refer to this report as the **2017 CAEFISS Report** as we analyse it here.

This annual report is in the same format (with significant deletions) as the previously published, Sept. 2018, *Vaccine safety surveillance in Canada: Reports to CAEFISS, 2013–2016*. We will refer to this report as the **Summary Report** as it summarizes 4 years of data.

We critiqued the format and content of the Summary Report extensively in the *Review of the 2018 CAEFISS Summary Report* found on our website. The new format made comparisons to previous reports difficult.

One main concern with the 2017 Report is that we are **once again presented with an entirely new set of numbers for AEFI reports** for 10 years of vaccine safety surveillance. This is clear from our chart in the Introduction to this report. Below is Figure 1 from the 2017 CAEFISS Report.

Figure 1: Total number of adverse events following immunization reports and reporting rate by reporting source and year, 2007–2017[a]

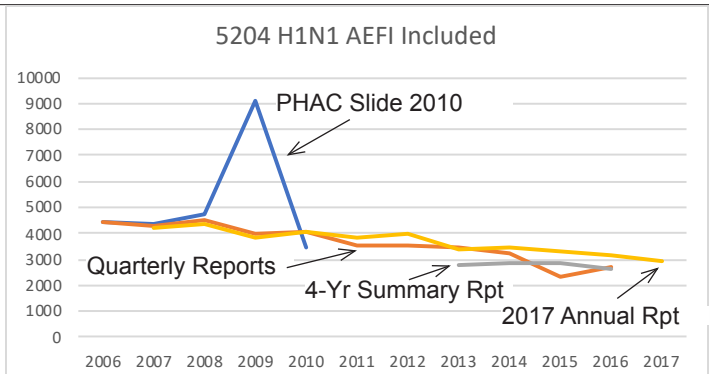


	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Active system	118	93	115	112	114	100	101	131	109	133	116
Passive system	4,091	4,295	3,734	3,934	3,721	3,901	3,316	3,306	3,193	3,047	2,844
Total	4,209	4,388	3,849	4,046	3,835	4,001	3,417	3,437	3,302	3,180	2,960
Reporting rate	17.9	21.9	17.8	18.3	16.2	16.9	15.5	14.9	13.5	12.8	12.6

Abbreviation: AEFI, adverse event following immunization
* Does not include the H1N1-09 pandemic influenza AEFI reports

The note tells us that the 2009 H1N1 AEFI reports were excluded. If they were included the year 2009 data would extend off the chart to over 9000 AEFI reports.

Below is what a comparison chart would look like with the 5,204 H1N1 AEFI data included, as it was in the 2010 PHAC slide. While CAEFISS reports note this exclusion as seen above, none have graphically represented it as we do here.



Instead of hiding this data, public health officials should consider what really occurred in Canada during this "Swine Flu Pandemic". As this November 20, 2009 article in the Toronto Star, titled ***How they larded H1N1 facts with fear***, reports:

"Months of dire swine flu warnings were a dangerous, disruptive cry of "wolf" for an ailment Canadian health officials knew would be a mild, manageable beast.

That's the pointedly caustic judgement of Dr. Richard Schabas, a one-time provincial health officer who says flu experts knew in July that H1N1 would hold little threat for Canadians this fall.

Schabas, now Medical Officer of Health for Hastings and Prince Edward Counties [Ontario], *says many of his colleagues fed a credulous media with worst-case warnings while downplaying the flu strain's relative weakness."*

Of particular importance is this quote from Dr. Schabas in the article [emphasis ours]:

*"While mortality rates among people 20 and younger in Canada will be slightly higher than in a normal flu season, **the actual number of deaths among healthy youngsters will be in the range of just seven**, Schabas says."*

Now ask yourself how many healthy children were injured by the over 5000 adverse events related to this fast-tracked vaccine. Especially consider this 2015 peer-reviewed article in CMAJ titled, *H1N1 vaccine and narcolepsy link discovered*, which states:

*"Rates of narcolepsy after the H1N1 pandemic were very low in Canada. A study in Quebec found that **seven cases** were associated with vaccination, for a rate of about one case per million vaccine doses, 1.5 to 2 times higher than normal. The vaccine used in Canada was Arepanrix, manufactured by GlaxoSmithKline, which "likely has the same amount of nuclear protein" as Pandemrix, said MacDonald."*

So in Quebec alone more children were injured with a life-long disability of narcolepsy than Dr. Schabas estimated would die of the disease in all of Canada.

New numbers for AEFI reports.

The Summary Report was conspicuously low in AEFI report numbers. The new numbers in the 2017 Report alternate between being higher or lower than previously reported numbers for the same years.

Comparing the various report numbers, there seems no rhyme nor reason to the differences. All we can really conclude is that the AEFI data is being managed. That is, data is groomed in various reports to meet some unknown standard for presentation to the public at different times.

Information removed from the 2017 Report

Shockingly, the 2017 Annual Report in its new format has **no data on the number of AEFI reports for suspect vaccines. This information has been completely and egregiously removed from the 2017 Annual Report, even though it appeared as Table 5 in the Summary Report.** The table below is reproduced from our 2016 Vaccine Safety Report, but cannot be updated since the information is no longer available to the Canadian public. Why is this information, which is vital for parents considering vaccination decisions, no longer available to the public in the new format CAEFISS reports?

Table 1 in the Summary Report gave the historical numbers of AEFI **reports and reporting rates by age group**. It has also been removed from the 2017 Report.

Also gone is Figure 4 that not only had a bar chart of Serious and Non-serious reports in each subcategory, but also gave all the SAE report numbers in the text description.

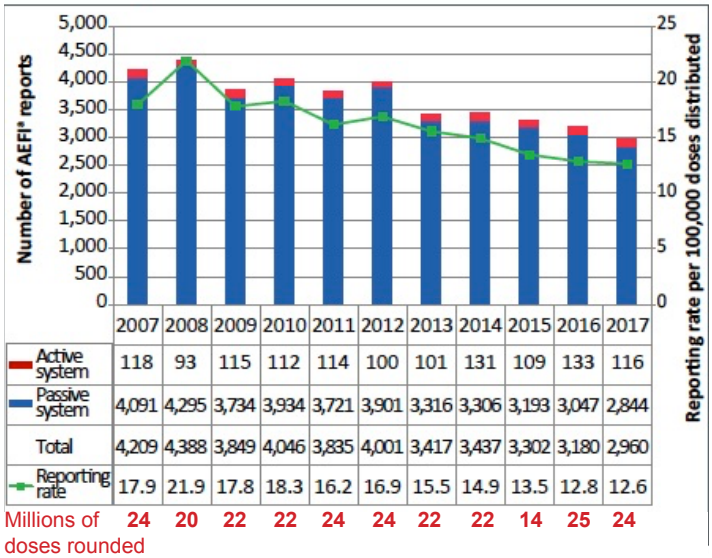
Basically, any information on SAEs is hard to come by in the 2017 Report. **And all age-related information for SAEs and most for AEFIs has vanished.**

2017 AEFI Report numbers

CAEFISS received a total of 2,960 AEFI reports in 2017. Total AEFI report numbers and per dose reporting rates for 11 years appear in Figure 1 above.

Below the figure in red text, we show the calculated number of doses distributed (i.e., purchased vaccines) each year. It is interesting that dose numbers have remained relatively stable (range 20–24 million doses) over the years. The exceptions are 2015 with only 14 million doses and 2016 with 25 million doses (perhaps to make up for the previous years 'shortfall').

Figure 1: Total number of adverse events following immunization reports and reporting rate by reporting source and year, 2007–2017[a]



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
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Passive system	4,091	4,295	3,734	3,934	3,721	3,901	3,316	3,306	3,193	3,047	2,844
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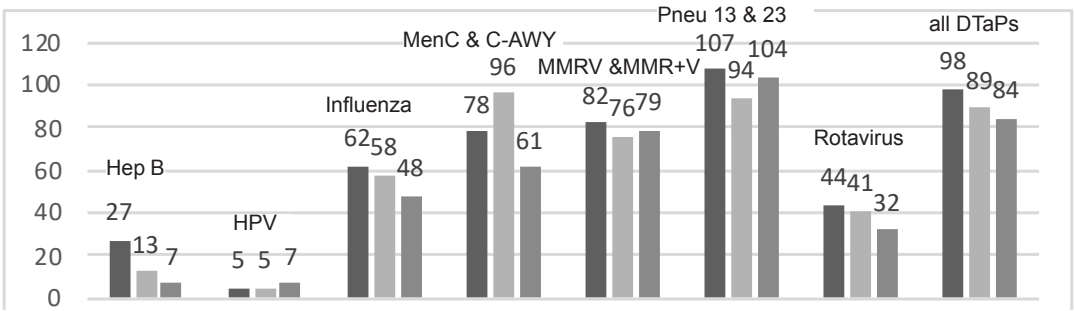
Reporting rate	17.9	21.9	17.8	18.3	16.2	16.9	15.5	14.9	13.5	12.8	12.6
Millions of doses rounded	24	20	22	22	24	24	22	22	14	25	24

One wonders if this tight range of doses purchased is a reflection of vaccine budget constraints, since one would expect the number of doses to vary with population growth and vaccine schedule increases over this time span.

Comparing the Figure 1 dose-based reporting rate for 2007 of 17.9 and 2017 of 12.6, both of which had the same number of vaccine doses distributed, it is clear that reporting rates have declined significantly.

It is also clear that reporting rates do not depend only on the number of doses distributed. Years with the most vaccine doses distributed do not have the highest reporting rates, nor do years with the fewest doses distributed have the lowest reporting rates. In fact it is quite the opposite. The highest reporting rate of 21.9 is recorded in 2008, yet that year had the second lowest number of doses distributed (20M) of the 11 years in the chart. Also in 2016 the highest number of doses distributed (25M) resulted in a reporting rate of 12.8 that was significantly lower than the reporting rate of 13.5 in 2015 with the lowest number of doses distributed (14M). So other factors are affecting the reporting rates.

CAEFISS SAE Reports by Suspect Vaccine: 2016, 2015 & 2011-2014 Average



As to the new historical numbers of AEFI reports seen in the 2017 report, we have no information about what these reports contained. For example, our previously published pie charts of Serious AEFI reports for age groups in 2015 & 2016 were based on breakdowns of the Quarterly Report total numbers of 2293 and 2685, respectively. Not on the total numbers now given as 3302 and 3180, respectively. **We have no idea how many of the extra 1009 AEFIs now reported for 2015 or the extra 495 AEFIs now reported for 2016 represented serious adverse events, nor which age groups experienced them.** Thus we cannot revise those pie charts.

Basically, the printing of new AEFI total numbers for the last 10 years invalidates all of the previous CAEFISS reports and the comparisons and data discussions we made in our own reports.

What we are seeing over time with the CAEFISS reports in their various iterations is a slow removal of vaccine safety surveillance information from the public eye. We are only being given very selective information. We suggest the public look at the last comprehensive and useful, 17-page 2012 Annual Report. It was published by CAEFISS in 2014, before the drive to combat 'vaccine hesitancy' began in earnest. In four short years, most of the useful data has been removed or obscured in the CAEFISS reports. Unlike the CV database where the public has access to AEFI reports, CAEFISS AEFI reports are all kept behind closed doors. The public's only access to the bulk (>80%) of Canadian adverse events information is through these increasingly nontransparent and uninformative reports.

2017 SAE Report numbers

The actual overall number of SAE reports and the overall reporting rate is given in the Abstract at the beginning of the report, as follows:

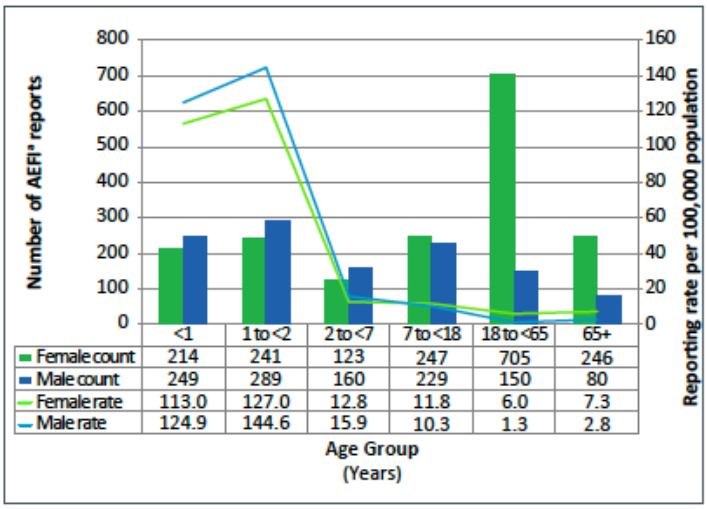
"Overall, there were 253 SAE reports, for a reporting rate of 1.1/100,000 doses distributed in 2017."

Note that serious adverse events are not 'one in a million' as is so often stated, but over all age groups they occur in just over 1 person for every 100,000 vaccine doses distributed. Specifically, 253 Canadians were reported to experience either death or life threatening events or were hospitalized or permanently disabled or had a baby with congenital defects in the SAE reports received in 2017. Since only a small percent of actual serious events are reported, more than 10,000 Canadians could have actually experienced serious events in 2017.

AEFI Numbers and Reporting Rates by Age Groups

Moving on to the next section of the 2017 report, the public is given the following figure to unravel.

Figure 2: Number and reporting rate of adverse events following immunization reports by age group and sex, 2017[a]

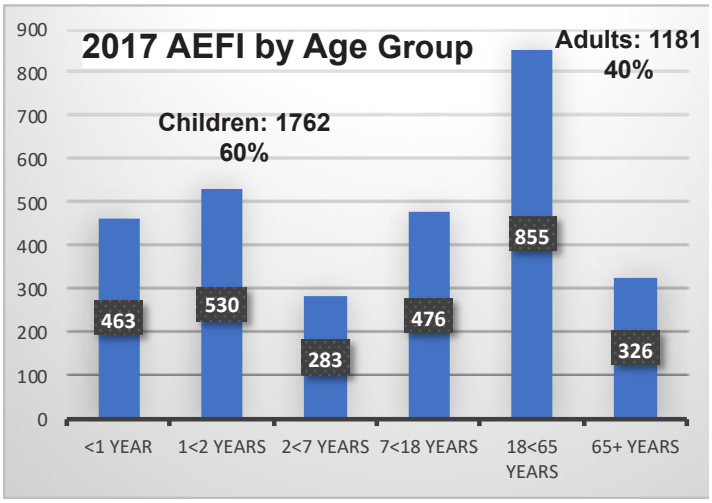


	<1	1 to <2	2 to <7	7 to <18	18 to <65	65+
Female count	214	241	123	247	705	246
Male count	249	289	160	229	150	80
Female rate	113.0	127.0	12.8	11.8	6.0	7.3
Male rate	124.9	144.6	15.9	10.3	1.3	2.8

Abbreviations: AEFI, adverse event following immunization; <, less than; +, and above
[a] Eighteen reports with missing age, nine reports with missing sex and one report indicating sex as "other" were excluded

The bars represent the male and female reports in each age group. The lines represent the reporting rates of AEFIs per 100,000 population by gender for each age group. Looking at just the lines it is easy to see that, as always, the highest reporting rates are for babies and infants less than 2 years of age, either gender. Note that the reporting rates for adults (the last two groups) are all single digit numbers, very low compared to the two youngest age groups.

While gender-based reporting is important for vaccine adverse events, it is equally important to see report numbers and reporting rates for the entire age group. When we do a chart for total reports by age group, we see the following:



Determining the reporting rates, is another matter. Reporting rates are important as they remove the bias

of the different population size for each age group. There are many more people in the age group from 18 to 65 than in any other group, so of course they have the most reports; but they actually have the lowest gender based reporting rates in Figure 2. In the report, total (genderless) 2017 reporting rate by age groups is only given for the youngest children and not for other age groups, as follows:

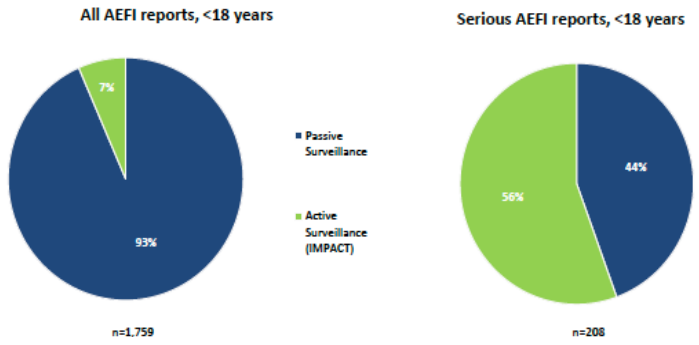
"The highest reporting rates were seen in children one to less than two years of age (136.5/100,000 population), followed by infants less than one year of age (119.6/100,000 population)."

Supplemental Data: SAE Reports

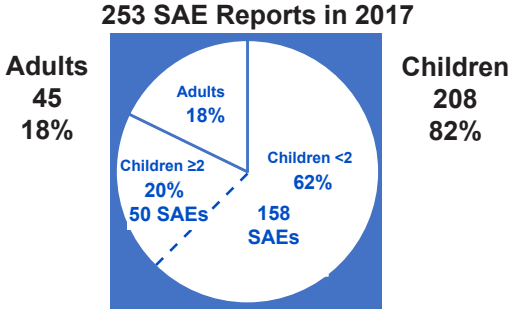
The very last line of the 2017 Report says that supplementary appendix information regarding reporting rates by age groups and number of SAE reports for children can be requested by email. We requested the information and received two figures.

The first figure gives the number of Serious Reports for children as 208 reports, representing 7% of all AEFI reports for children. Passive surveillance reported 44% and Active surveillance reported 56% of the reports.

Figure A1: Proportion of adverse events following immunization reports by active versus passive surveillance in children less than 18 years of age, 2017

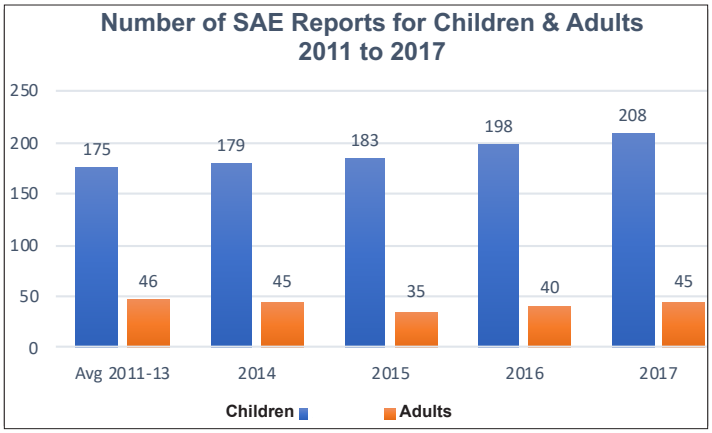


However, the SAE information that is <u>not</u> reported is represented by the following pie chart we created where we see that the 208 reports for children represents 82% of the total 253 SAE reports.



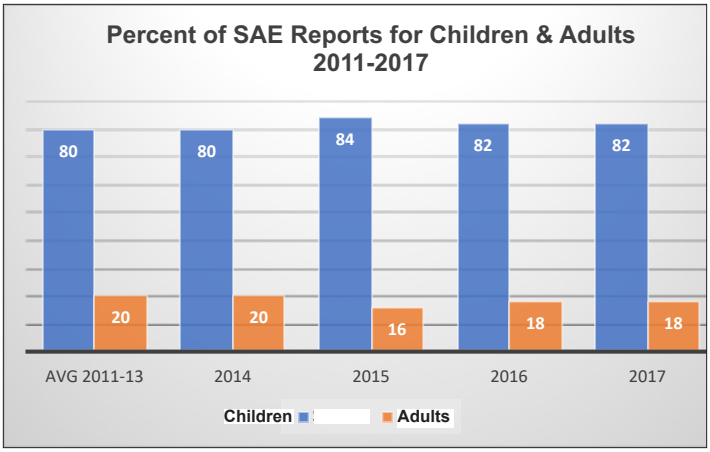
Is the reason to not include this information in the report so parents making vaccine decisions don't see it? Especially parents who are aware that 208 SAE reports represents only a small portion of the **actual** serious events that were likely experienced by children in 2017 alone. If 1% of actual serious events are being reflected by passive surveillance reports and 10% by active surveillance reports, then 9930 children could have actually been affected in 2017 alone.

To get a sense of what this means over time for Canadian children, we created the two bar charts below from previously published CAEFISS Quarterly Report data. Only 2017 is the new data.



Over the 7 years in this chart, the number of SAE reports (n=943) means almost 1000 children reportedly suffered serious injury (or death) following vaccination. Using the 1% passive and 10% active rates of **actual** serious events and the active/passive percentages given in Figure A1, we can estimate that **over 42,000 children experienced actual serious adverse events during this 7-year time span.**

In the next chart the percent of SAE reports for children and adults has remained fairly stable over this time span: Range 80–84% for children, 16–20% for adults. We have no reason to expect SAEs to reduce in number, since no effort is being made to change the vaccine schedule so fewer babies are impacted or to determine children who may be more susceptible to vaccine injury or to make vaccines safer.



If the new 2017 data could have been used in our two charts, the number of SAE reports would likely be

higher, especially for 2012, 2015, 2016 with significantly more total AEFI reports as shown in the table to the right.

Of course we cannot use this data because it was never included in previous CAEFFIS reports that would have told us how many of theses reports were serious and non-serious, what the injuries were what vaccines were involved and what age groups were affected.

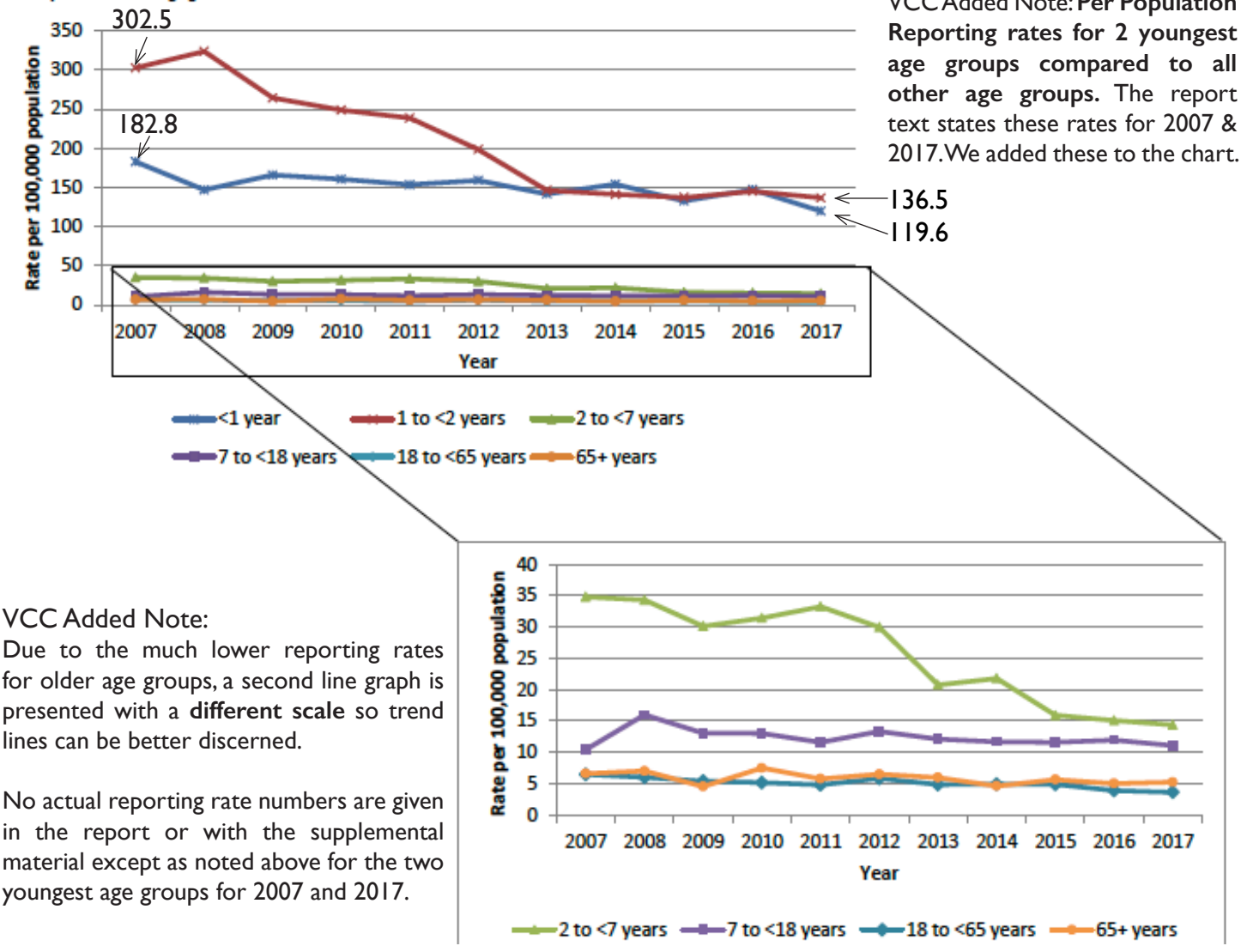
Year	Quarterly Reports	2017 Annual	Difference
2007	4258	4209	–49
2008	4482	4388	–94
2009	4009	3849	–160
2010	4046	4046	0
2011	3558	3835	+277
2012	3508	4001	**+770**
2013	3491	3417	–74
2014	3242	3437	+195
2015	2293	3302	**+1009**
2016	2685	3180	**+495**

Supplemental Data: AEFI Reporting Rates by Age Group

The second supplemental appendix graphic we received is included below. There was no text with the actual reporting rates accompanying this graphic. Basically we have to guess at what the actual rates are. For example looking at 2008, it appears that the reporting rates for 1 to <2 year olds (red line) is approximately 325/100,000 population. Really we can only see the trend lines since the actual reporting rates are not included with the chart.

Figure A2: Annual reporting rate of adverse events following immunization reports by age group, 2007-2017[a]

[a]18 reports with missing age are excluded.



VCC Added Note: **Per Population Reporting rates for 2 youngest age groups compared to all other age groups.** The report text states these rates for 2007 & 2017. We added these to the chart.

VCC Added Note:
Due to the much lower reporting rates for older age groups, a second line graph is presented with a **different scale** so trend lines can be better discerned.

No actual reporting rate numbers are given in the report or with the supplemental material except as noted above for the two youngest age groups for 2007 and 2017.

We generated the graphs below using the previously published data to see the difference in reporting rates and trends between the new data and the previous data.

Comparing the 1 to <2 year 2007 starting point on the two line charts, the reporting rate on their chart is 303/100,000 population. On our chart it is lower at 276/100,00 population. In 2008, their chart shows an increase to perhaps 325/100,000, ours an increase to 283/100,000. Yet they are using lower report numbers for these years as our number table on the previous page shows.

Moving to 2010, our number table on the previous page shows that the **same number of total reports** (4046) was used in both previously published data and the new 2017 data. Therefore, one would expect reporting rates to be the same on both line charts. But they are not! The reporting rates in their Figure A2 are consistently higher, as shown in the following table with **different rates generated from the same data**.

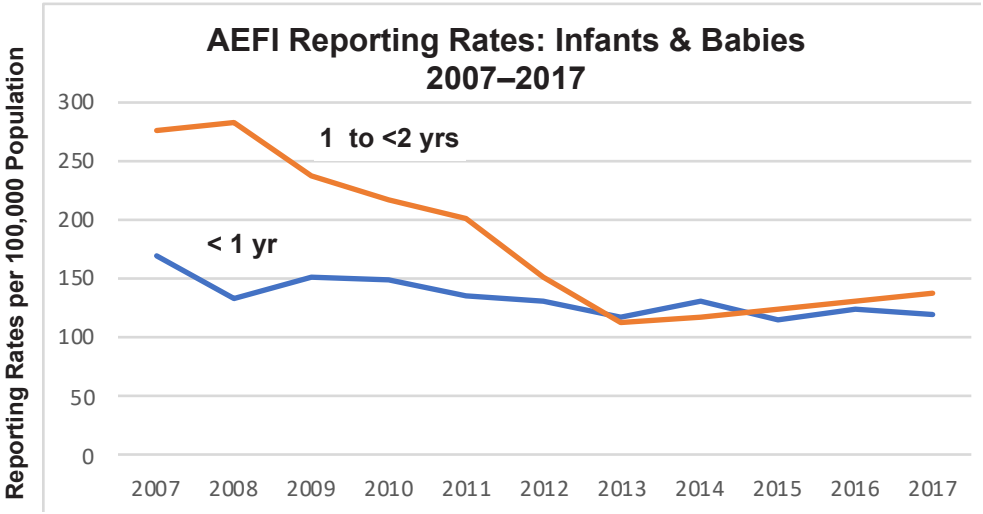
Total AEFI Reports in 2010 were 4046 in both previously published and new data. Using this number, the reporting rates generated in the CAEFISS Figure A2 compared to previously published CAEFISS reporting rates should be the same.

Age Group	2010 Reporting Rates/100,000 Pop.	
	Figure A2	Previously Published
<1	160?	150
1 to <2	250	217
2 to <7	32?	28.7
7 to <18	13?	12
18 to <65	5	4.7
65+	8?	7.1

We can think of no logical explanation for this anomaly since reporting rates are calculated with the number of reports for the age group in the numerator and the population for the age group in the denominator.

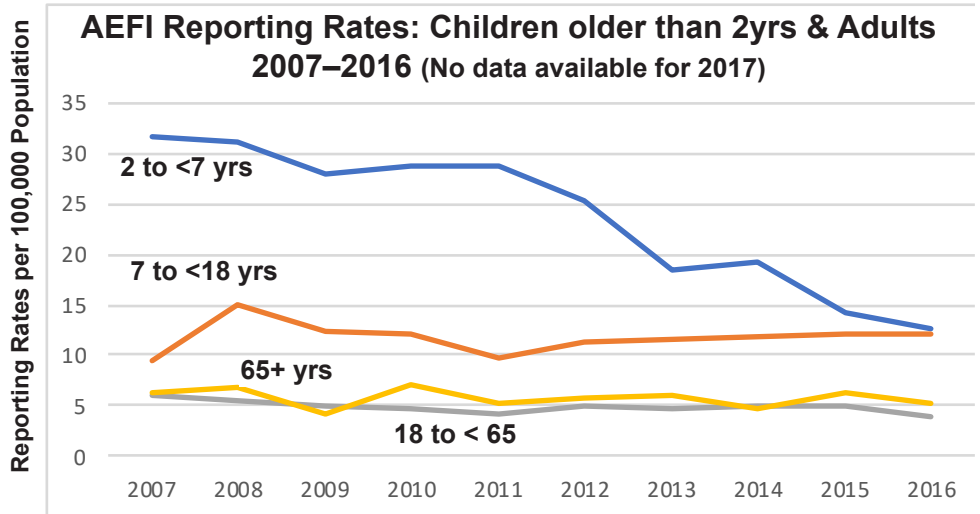
As to trend lines for reporting rates, they are a bit different in the two sets of charts, but this would be expected with different numbers of AEFI reports being used in each (except for the year 2010).

For example, in 2015 there are over 1000 more reports represented in the Figure A2 chart, and in 2016



Year	<1	1–<2
2007	169	276
2008	134	283
2009	152	238
2010	150	217
2011	136	201
2012	130	152
2013	118	113
2014	131	118
2015	114	125
2016	125	131
2017	120	137

CAEFISS Data Used: Years 2007–2012 came from Table 3 in the 2014 Summary Report. Years 2013–2016 came from Table 1 in the 2016 Summary Report and 2017 from text in the 2017 Annual Report.



Year	2 to<7	7 to <18	18 to <65	65+
2007	31.5	9.5	6	6.3
2008	31	15.1	5.6	6.8
2009	27.8	12.3	4.9	4.3
2010	28.7	12	4.7	7.1
2011	28.8	9.7	4.2	5.3
2012	25.2	11.2	5	5.8
2013	18.3	11.5	4.8	6
2014	19.3	11.8	5	4.7
2015	14.1	12.2	5.1	6.2
2016	12.5	12.2	4	5.3

CAEFISS Data Used: Years 2007–2012 came from Table 3 in the 2014 Summary Report. Years 2013–2016 came from Table 1 in the 2016 Summary Report. No 2017 reporting rate data was given for these 4 age groups in the 2017 Annual Report.

there were almost 500 more. Looking at the trend lines for the youngest two age groups in Figure A2, the lines are trending together in those two years. In our charts with the lower number of reports, the <1 yr old line is below the 1 to <2 year old line. This difference would indicate that many of the new reports in Figure A2 were for the less than <1 age group to bring the line up to the same reporting rate as the older group for those two years.

This reporting rate by age group figure should have been published in the main body of the report (not requiring an email to obtain it). And the age group data that was used to generate the figure should also have been published as was done in all previous CAEFISS reports. The SAE report numbers should also have been printed in the report and reported by age group.

Primary Reason for Reporting

The next section of the report is Table 2 reproduced for the reader below. We laboriously discussed this not useful table in our critique of the Summary Report.

Table 1: Frequency of reports and percent that is serious for each primary adverse event following immunization sub-category, 2017

Primary AEFI category	Primary AEFI sub-category	Number of reports (N=2,957)[a]	Serious event (%)
Allergic or allergic-like events	Anaphylaxis	33	100
	Other allergic events[b]	355	1
	Oculo-respiratory syndrome (ORS)	28	0
	Rash	1	0
	TOTAL	417	9
Infection/ syndrome/ systemic symptoms (ISS)	Fever only	11	27
	Infection	28	36
	Influenza-like illness (ILI)	10	0
	Rash with fever and/or other illness	61	10
	Syndromes (e.g., Kawasaki)	16	88
	Systemic (when several body systems are involved)	55	11
	TOTAL	181	22
Neurologic events	Aseptic meningitis	3	67
	Ataxia/cerebellitis[c]	2	50
	Bell's palsy	6	17
	Encephalitis / acute disseminated encephalomyelitis (ADEM) / myelitis	5	100
	Guillain-Barré syndrome (GBS)	2	50
	Other paralysis lasting more than one day	1	100
	Seizure	111	52
	Other neurologic event[d]	47	17
	TOTAL	177	44
Rash alone	Generalized	291	0
	Localized	35	0
	Location not specified/ extent unknown	20	0
	TOTAL	346	0

Table 1: (*continued*) **Frequency of reports and percent that is serious for each primary adverse event following immunization sub-category, 2017**

Primary AEFI category	Primary AEFI sub-category	Number of reports (N=2,957)[a]	Serious event (%)
Immunization anxiety	Presyncope	6	0
	Syncope	33	6
	Other anxiety-related event[e]	7	0
	TOTAL	46	4
Vaccination site reactions	Abscess (infected or sterile)	13	31
	Cellulitis	329	5
	Extensive limb swelling (ELS)[f]	136	2
	Pain in the vaccinated limb of seven days or more	56	0
	Other local reaction[g]	804	2
	Rash	1	0
	TOTAL	1,339	3
Vaccination error	Vaccination error TOTAL	3	0
Other	Arthralgia	16	0
	Arthritis	5	20
	Gastrointestinal event	169	5
	Hypotonic-hyporesponsive episode (HHE)	17	24
	Intussusception	6	83
	paraesthesia		
	Parotitis	9	0
	Persistent crying	16	6
	Sudden infant death syndrome (SIDS)	0	N/A
	Sudden unexpected/ unexplained death syndrome (SUDS)	0	N/A
	Thrombocytopenia	25	80
	Other events[h]	163	12
	TOTAL	448	13

The only change that has been made to this Table is that totals have been added to each sub-category. While this is useful, it is done at the expense of removing Figure 4 that was in the Summary Report and contained both the number and percent of both SAE and AEFI reports for each subcategory. This is a most unwelcome omission of data.

The text in the report regarding this table is particularly disturbing for two reasons. It says.

"Excluding the 'other' category, the most common primary AEFIs reported for vaccines administered in 2017 were vaccination site reactions (n=1,339, 45%) followed by allergic reaction (n=417, 14%) and rash alone (n=346, 12%)(Table 1).

"The proportion of serious events was highest for the neurological event category (44%), followed by infection/ syndrome/systemic symptoms (ISS) (22%)."

Both of these statements draw the reader's attention away from very important SAE information. Blithely "excluding" the 'Other' category, which has more AEFI reports than either the second or third category they choose to note is blatant obfuscation. While we

understand why they did this, namely that for the first time the number of reports in the 'Other" category has exceeded the number of reports in the Allergic category, we cannot condone it.

The second statement regarding only the percent of SAE reports (and not the number of SAE reports) in the two highest categories, also obfuscates the data in the 'Other' category. First by not mentioning it as the 3rd highest category by percent, but mostly because percentages based on different data are not really comparable. For example, 50% of 100 SAE reports is 50 reports. Whereas 25% of 200 SAE reports is also 50 reports. The percentages alone do not tell us how many reports are involved.

We made the following table by recording the number of AEFI reports and the % of SAE reports in each subcategory of Table 1 and then calculating the number of SAE reports. **The categories are ranked by the number of SAE reports (highest first), rather than by percentages.**

Event	# AEFI	%SAE	#SAE
1. Neurologic	177	44%	78
2. Other	448	13%	58
3. ISS	181	22%	40
4. Vac Site	1339	3%	40
5. Allergic	417	9%	38
6. Anxiety	46	4%	2
7. Rash alone	346	0%	0
8. Vac Error	3	0%	0

This presents a very different picture than given by the text since 'Other' has the 2nd highest number of reports and ISS the 3rd highest. Of interest, Vaccination Site events are always alluded to as non-serious or of little concern, but they actually rank 3rd in the number of SAE reports (sharing that position with ISS events).

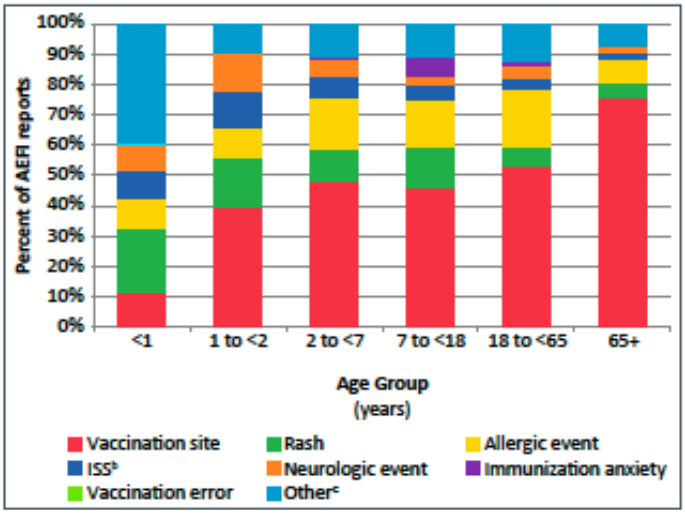
However, the first 3 categories and the 5th are arguably more likely to result in more serious and/or permanent conditions than vaccination site events. We will see other implications of those two text statements as we look at the next figure in the report.

Figure 3 in the report shows the distribution of their Table 1 reports by age group. The accompanying text says:

"Vaccination site reactions represented the greatest number of AEFIs for all the age groups except for children less than one year of age. Excluding the "other" event category for children under one year of age, the most commonly reported AEFI was rash alone, followed by vaccination site reactions (Figure 3)."

Here is figure 3 as it appears in the report (minus the tiny notes).

Figure 3: Distribution of primary adverse events following immunization reported by age group, 2017[a]



Yes, they did it again! The reader is told to ignore the largest category of events for babies under one year of age. It appears 40% of reports are in the 'Other' (blue) category for infants and babies <1 year old.

The quote above is the only thing the 2017 report says about this figure.

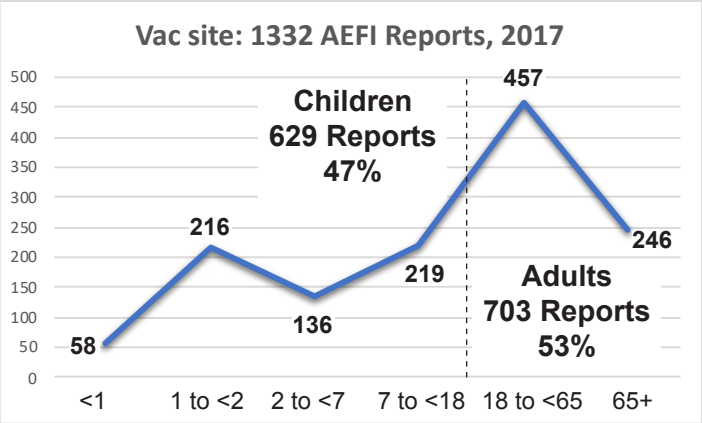
The text description (in the on-line version only) contains the percentages of each colored bar. However, this text description does not contain the total number of reports for each age group. The text description in the previous Summary Report **did** contain this information, which is essential to understanding the percentages, as we explain and show above.

On the next page are a series of line charts we created after calculating the number of reports for each type of event. These charts give another picture of the number and type of events experienced in each of the six age groups.

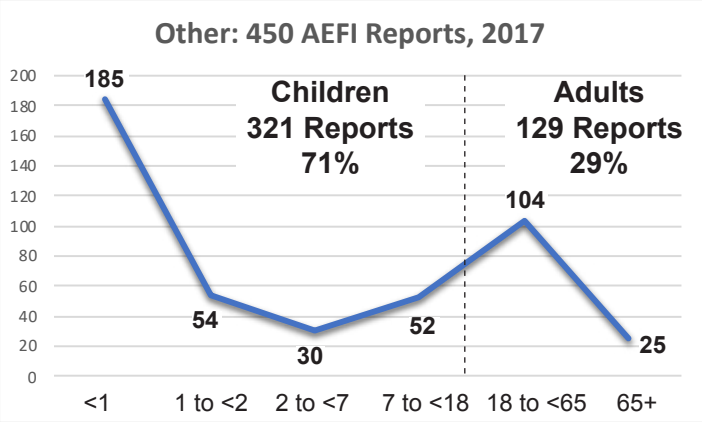
There were a total of 2960 AEFI Reports in 2017. The line charts are arranged in order of frequency and percent of total reports for event types. There is no chart for the three Vaccination Error reports.

Event	# AEFI	% of Total AEFI
1. Vac Site	1332	45%
2. Other	450	15%
3. Allergic	415	14%
4. Rash only	347	12%
5. ISS:	186	6%
6. Neurologic	180	6%
7. Anxiety (Syncope)	46	2%

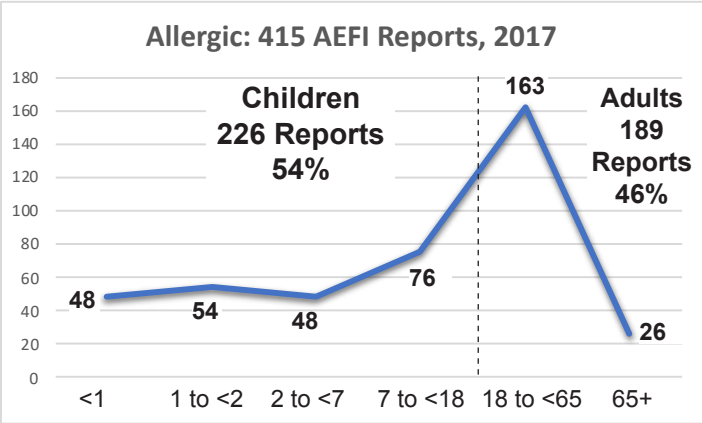
Vaccination site reactions were the most common AEFI. This is the only chart where children did not experience a majority of AEFIs, although they did experience almost half of these reactions.



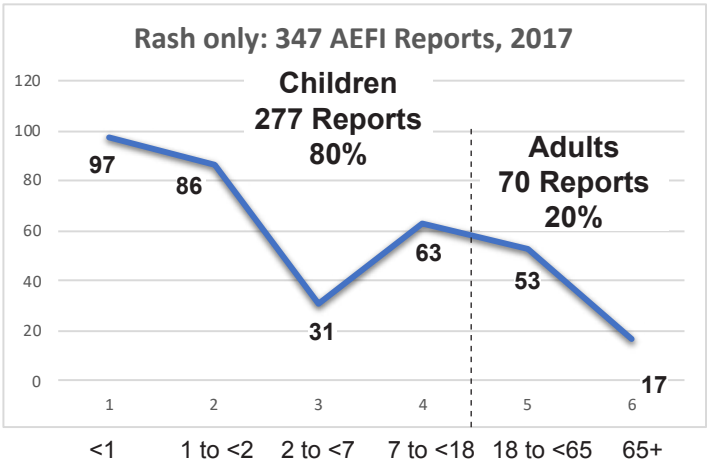
The 'Other' event category is the information that the text would like to 'exclude' when looking at AEFI reports for children less than one year old. Yet this group suffered 185 (41%) of these adverse events including such serious events as intussusception, HHE, thrombocytopenia, SIDS and so forth.



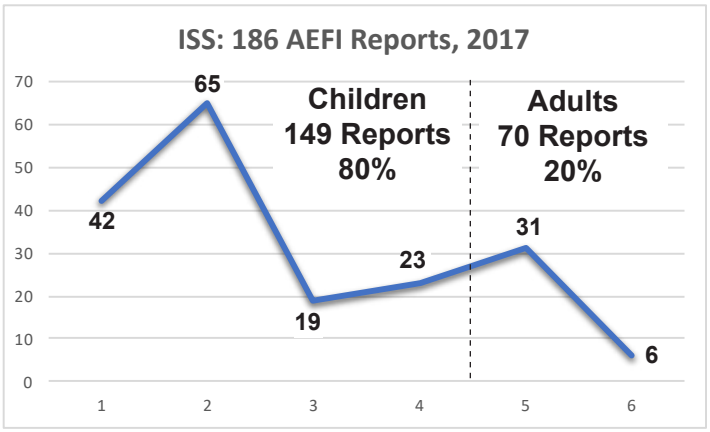
It is notable that older children (7 to <18 year olds) suffered more **Allergic** reactions than younger age groups, perhaps because this is the age group that receives HepatitisB and Tdap boosters, HPV and Meningococcal-ACYW-135 in school vaccination programs.



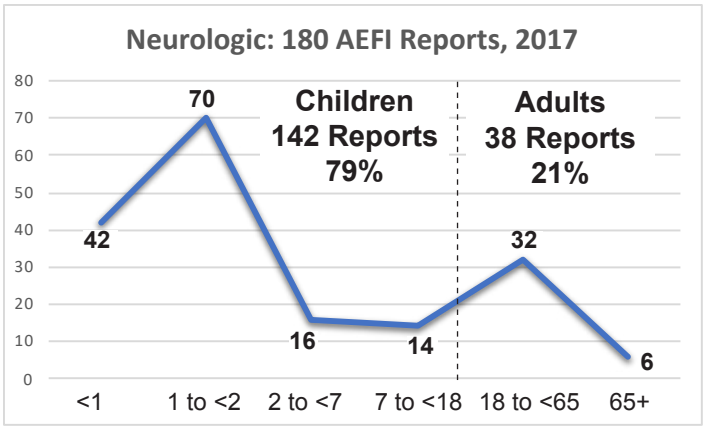
Rashes are an allergic, inflammatory reaction, usually defined in case definitions as Systemic Events. However CAEFISS chooses to list them separately.



Infections, syndromes and systemic reactions (ISS) are often serious. They include Kawasaki syndrome, fibromyalgia, influenza like illness fatigue and lethargy and sepsis.



Neurologic adverse events had the most number of serious reports. This is understandable considering this category contains ataxia (loss of muscle control), seizures, meningitis, encephalitis and ADEM, and various forms of paralysis including GBS and Bell's Palsy.



But, despite this number-bashing, we are still left in the dark as to **how many of the reports in each group is Serious in nature.** This information is simply no longer available to the public in CAEFISS reports.

Health Care Utilization

Table 2 provides information on the level of health care sought after vaccination. This table gives only a partial picture since PHAC does not monitor physician visits for adverse events following vaccination. It reflects hospital and public health records only.

Table 2: Highest level of health care sought for adverse events following immunization, 2017

Highest level of care sought (N=2,709)[a]	n	%[b]
Required hospitalization (≥24 hrs)	197	7
Resulted in prolongation of existing hospitalization	1	<0.1
Emergency visit	639	24
Non-urgent visit	1,088	40
Telephone advice from a health professional	127	5
None	623	23
Unknown	34	1

Abbreviations: n, number; N, total number; <, inferior to; ≥, superior or equal to
[a] Two hundred fifty-one cases with missing information on highest level of care sought were excluded
[b] Percentages in table do not total 100% due to rounding

In order to compare this table to the previously published utilization table below from the Summary Report, it must be noted that the 'Missing' category of 251 reports (9%) was removed from the table. We recalculated all the percents based on **a percent of total number of reports of 2960** rather than the **2709 partial number of reports** used above. This lowered some of the percentages, though not significantly.

Table 3: Health care utilization sought for adverse events following immunization, 2013–2016

Highest level of care sought	N	%
Required hospitalization (>24 hrs)	764	7
Resulted in prolongation of existing hospitalization	4	<1
Emergency visit	2,126	19
Non-urgent visit	4,084	37
Telephone advice from a health professional	487	4
None	2,542	23
Unknown	323	3
Missing	750	7
Total	11,080	100

The main changes over 5 years were:

- 5% increase in Emergency room visits from 19% in the previous 4 years to 24% in 2017
- 3% increase in non-urgent visits from 37% to 40%.
- For a total **8% increase in emergency room visits**—whether urgent or non-urgent—in 2017.

Outcome

These tables from the 2017 Report and the 2013–2016 Summary Report show the outcome when it was recorded. Note the 2017 Report again removed the number of reports (82 or 3% of total number) that were missing this information from the table.

The main Outcome differences between 2017 and the previous 4 years are a 1% decrease in full recovery and a 2% increase in those not yet recovered.

Table 3: Outcome at time of reporting for all adverse events following immunization reports, 2017

Outcome (N=2,878)[a]	n	%[b]
Fully recovered	2,154	75
Not yet recovered at time of reporting	589	20
Permanent disability / incapacity	1	<0.1
Death	4	0.1
Unknown	130	5

Abbreviations: n, number; N, total number; <, inferior to
[a] Eighty-two cases were missing information on outcome, therefore were excluded
[b] Percentages in table do not total 100% due to rounding

Table 4: Outcome at time of reporting for all reports, 2013–2016

Outcome	N	%
Fully recovered	8,464	76
Not yet recovered at time of reporting	1,948	18
Permanent disability/incapacity	12	<1
Death	32	<1
Unknown	532	5
Missing	92	<1
Total	11,080	100

Abbreviation: N, number

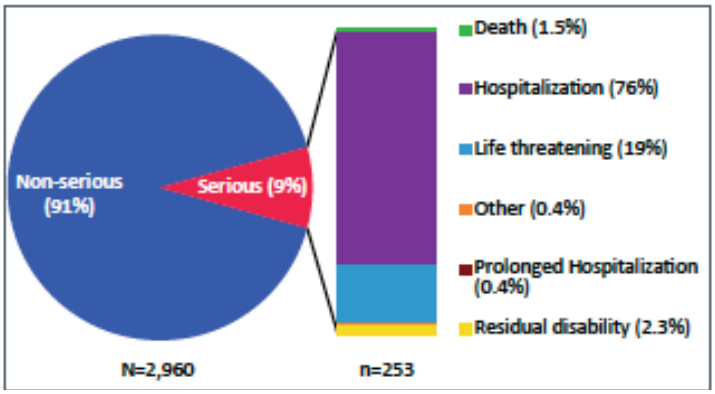
In the five years covered by these two reports, AEFIs recorded include 36 deaths, 13 permanent injuries and over 2,500 people not recovered from injuries at time of reporting. Were 81% of these adverse events experienced by children? We only know from the reports that 20 deaths (55%) occurred in children in these five years. The age of sufferers and type of disabilities and injuries from which they did not recover are not revealed.

Serious Adverse Event Reports

The introduction to the 2017 Report says, "*The objective of this report is to provide a) a descriptive analysis of AEFI reports for vaccines administered in Canada in 2017, b) a descriptive review of health care utilization and outcome following an AEFI and c)* ***an analysis of serious adverse events (SAEs).***" [emphasis ours]

As we have discussed, information on Serious Adverse Events (SAEs) is very limited. The final figure in the report shows a breakdown of SAE reports and is shown on the next page.

Figure 4: Classification of serious adverse events reports, 2017[a]



Here is the report text following this figure, interspersed with our clarifying comments:

"Among the SAE reports, the most frequently reported primary AEFI was seizure (n=58, 23%), followed by anaphylaxis (n=33, 13%)."

The 2013–2016 Summary Report notes, *"the most frequently reported primary AEFI was seizure (20.1%), followed by anaphylaxis (12.4%)."* So 2017 SAE reports for seizures and anaphylaxis increased as a percent of all SAE reports from the previous 4 years. The text continues:

"The majority (n=183, 72%) of SAE reports had fully recovered at the time of reporting. For those patients who had not fully recovered at the time of reporting, these reports were revised if updated information was received by CAEFISS from the provinces and territories. Other outcomes for SAE reports included fatal outcome (n=4, 2%), permanent disability/incapacity (n=1, 0.4%), unknown outcome (n=15, 6%) and missing information on outcome (n=5, 2%)."

We calculated the 'not recovered' (since it was not mentioned in the text). We have combined the last two categories, Unknown and Missing Information, as both mean the same thing, namely that the outcome is not recorded. The patient may or may not have recovered.

Outcomes for 2017 SAEs	N	%
Fully Recovered	183	72%
Not Recovered	50	20%
Unknown/Missing info	20	8%

Continuing with the report text:

"The majority of SAEs were in children and adolescents less than 18 years of age (81%), with almost three quarters (74%) of these SAEs being reported in children under the age of two years."

We know from the supplemental material (page 6) that 208 of the SAE reports are for children, therefore 74% of these would represent 154 SAE reports for children less than 2 years old in 2017 and 54 SAE reports for children from 2 years old to < 18 years old.

The text continues,

"There were two deaths in those less than two years of age and two deaths in those 18 years of age and older. After careful review, all deaths were considered to be a result of pre-existing conditions (heart surgery, serious injury, cardiovascular disease, diabetes and hypertension) and not to the vaccines administered."

Therefore 2 babies and 2 adults died following vaccination in 2017, but no individual details are given. That is, which of the preexisting conditions of the five listed occurred in the babies? And the ever-present question arises of what actual proof exists that the pre-existing condition caused the death and that vaccination played no part. (See Part 4 on Causality.)

The final text says, *"There was also one reported outcome of disability that occurred in an individual. The medical history was reviewed for this individual and it was concluded, based on the information provided, that the disability was not considered to be related to the administered vaccine."*

First, the data in Figure 4 indicates that in fact there were **six instances (rather than only one) of 'residual disability' in 2017:** 2.3% of 253 = 6 reports. One report as indicated in the text would be only 0.4% of 253 total SAE reports. This anomaly between Figure 4 and the text is not explained.

Second, no information is given as to the actual disability for the one report mentioned, the vaccine given, the age of the recipient, or what this medical opinion is based on. Note they do not say it was caused by a pre-existing condition.

Also the 48 life-threatening events in Figure 4, representing 19% of the 253 SAE reports, are not mentioned in the text. What were they?

Finally, we note that the SAE reporting rate for all ages is given as 1.1/100,000 doses distributed. The SAE reporting rate for all children would be higher and for babies and infants less than 2 years old even higher still. However, these SAE reporting rates are not available in the CAEFISS report 'analysis' of SAEs.

The Discussion section of the report says that *"The greater proportion of SAEs seen in children under two years of age is likely due in large part to the number of vaccines provided to this age…"*. This statement certainly admits causality from vaccines, although that is as close as CAEFISS can come to discussing causality, the vaccine schedule and children's injuries and deaths. When it comes to specific injuries or deaths, the little comment there is in this report, seen in the text above, removes all causality from vaccines.

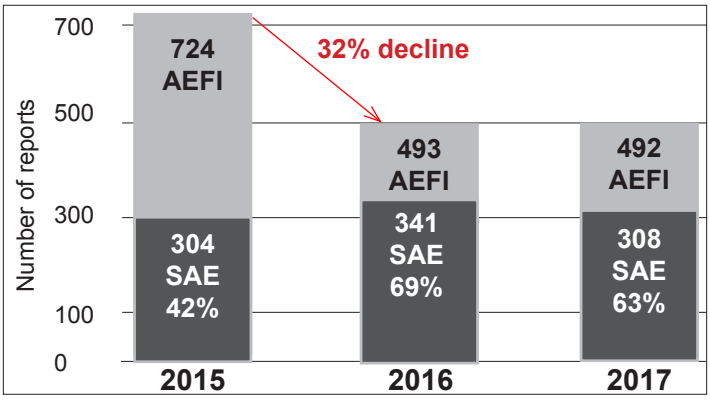
Part 2: Canada Vigilance Database Analysis

Adverse Events Following Immunization 2016 & 2017 Reports

The Canada Vigilance *Vaccine Safety Reports* are difficult to find on the internet. They are found in the index to MedEffect Canada's publication **Health Products InfoWatch**. The issues must be scrolled through to find the CV reports. The 4 reports for 2016 are linked directly here: **Q1**, **Q2**, **Q3** and **Q4**, and the 2 biannual reports for 2017 are linked directly here: **Jan to June** and **July to Dec**.

As usual there is minimal data in the Canada Vigilance vaccine safety reports. The figure below presents the overall data: Total number of AEFI reports and the percent and number of those reports that were Serious (SAE). As this is the database that manufacturers are required by law to report all serious reactions to, it is not unusual to have a high percent of Serious reports.

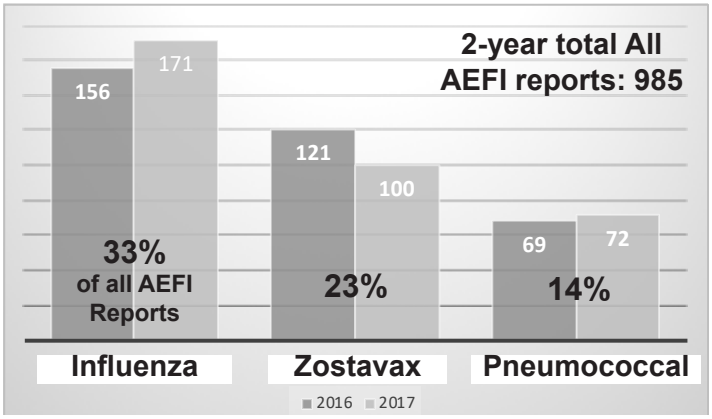
Fig. 1 2015–2017 Comparison: All Reports vs SAE



As we have stated previously, the population is increasing, the number of vaccines administered is increasing, yet adverse event report numbers are down.

The vaccines with the largest percent of AEFI reports in 2016/17 are shown below. The 3 vaccines shown account for 70% of all AEFI reports received for these two years.

Fig. 2. 2016–2017 Vaccines: Most Frequent AEFI



More Shots Means More Reactions

We detailed how we arrived at estimated numbers of these 3 most reported vaccines in our ***Vaccine Safety Report 3***, page 6. Suffice it to repeat here that those estimates are as follows:

- **13 Million Annual Influenza Vaccines to all ages**
- **4.2 Million Annual Pneumococcal Vaccines to babies and the elderly**
- **~200,000 Annual Shingles (Zostavax) Vaccines**

We know the shingles vaccine is highly reactogenic since we see so many reports from such a small number of doses.

Deaths in 2017 AEFI Reports

Here is the quote on these deaths from the CV July to December 2017 *Vaccine Safety Report* :

"There were 6 reports with an outcome of death. These reports involved patients between 19 and 70 years of age: 2 females, 3 males and 1 with unknown gender. One report was for Zostavax from a healthcare professional and 5 were for influenza vaccines from social media extracted by the company. The information provided was not sufficient to adequately assess the causal association with the vaccines."

"The company" in the above quote means the manufacturer or distributor of the vaccine. Very interesting they are "extracting" death data "from social media"! At the top of the next page you can see the Zostavax death report which was downloaded from the CV database. This death resulted from a heart attack in a 53 year old woman after receiving the Zostavax vaccine. Note how little information is contained in the report. This guarantees that causality cannot be found. The VAERS database in the US has numerous reports of death due to heart attacks following Zostavax injections, some within hours of vaccination.

Of interest regarding the 5 influenza vaccine deaths, the quote above states the ages range from 19 to 70 years of age. When the reports were downloaded from the database, only one report (for a 70 year old male) contained age data. The other four had no age data, and two of these had been hospitalized. It is obvious that the ages are known; but for some reason this information is being obscured on the "publicly accessible" database.

Reproduced on the next page is a serious report in a detailed format accessible on the database by clicking on the actual report number (but not accessible for downloading). As one can see, white boxes have been placed over the "Age" area and the "Weight" and "Height" areas. This is a report for a reaction to an

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2018-07-28 - 10:18:11 AM
Initial Received Date: 2017-07-01 to 2017-12-31
Latest Received Date: N/A
Total Number of Reports: 1 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_01468493	4	2017-09-05	2017-11-21	MAH	1708CAN013755	Spontaneous	Other Health Professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Yes	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Death

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
STERILE DILUENT	Suspect		Subcutaneous	1.0 Dosage forms			Product used for unknown indication
ZOSTAVAX	Suspect	POWDER FOR SUSPENSION SUBCUTANEOUS	Subcutaneous	0.65 mL		1.0 Day(s)	Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocardial infarction	v.21.0	

Detailed Report with age, age group, weight & height obscured

Detailed Adverse Reaction Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number:	E2B_01514156
Latest AER Version Number:	0
Market Authorization Holder AER Number:	CA2017GSK150774
Initial Received Date:	2017-10-04
Latest Received Date:	2017-10-04
Age:	
Age Group:	
Type of Report:	Published
Reporter Type:	
Source of Report:	MAH
Report Outcome:	Unknown
Gender:	Male
Weight:	
Height:	
Serious report?	Yes

White box, note top of grey area area showing

White box, note top of grey area area showing

Reason for Seriousness

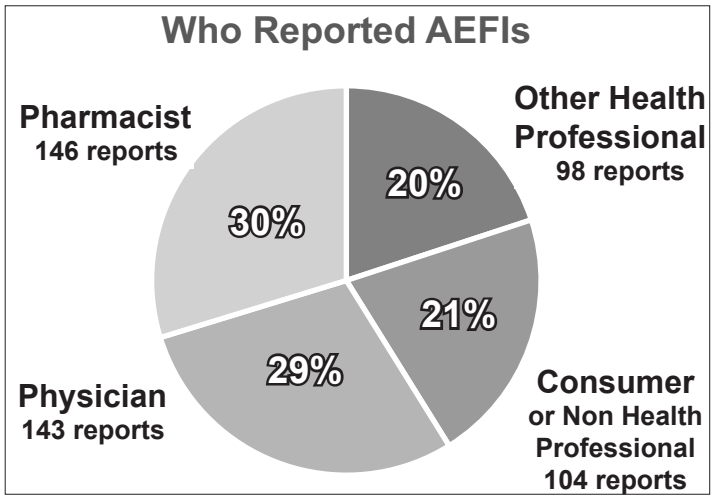
Death:
Hospitalization:
Life Threatening: Yes
Congenital Anomaly:
Disability:
Other Medically Important Conditions: Yes

influenza vaccine. It could be for a child or an adult. It did not result in death, but rather in a life-threatening event. That could mean anaphylactic shock, stroke or heart problems, etc. It also resulted in an "Other Medically Important Condition". This would be an unusual (unexpected) adverse event not listed in the product monograph.

Regardless, it is apparent that the administrators of the database are obscuring data from the public by placing white boxes over information. This also explains why they know the ages of the influenza deaths in the quote from their own report, but the ages do not appear in the reports of these deaths on the database.

Format Changes to CV Safety Reports

There are changes to the format of the CV Safety reports in their Biannual iteration. The first change is a pie chart showing who is reporting AEFIs in each half year. Recalculating for the total 2017 numbers results in the following pie chart.



In nine provinces, pharmacists (with training) can vaccinate those over the age of 5, largely with influenza and travel vaccines. In most provinces physicians administer recommended vaccines to babies and younger children and public health nurses administer vaccines to school-age children. Hospital nurses administer to those in hospital care.

The second change to the reports is a bar chart showing serious and non-serious AEFI reports by age groups. Previous reports did not have this information, so it is a welcome addition. However, the choice of age groups makes it impossible to compare to CAEFISS data except for the broad categories of all children, adults or the elderly. Combining the data from the two CV reports for 2017 results in the bar chart below.

If we group all ages of children together, they would account for 19.5% of all serious reports. All adults would account for 61% of all serious reports. And, most disturbingly, 19% of serious reports had no ages indicated.

Even if we were to add all the unknown ages to the all age children data, we would only see 38% of CV Serious AEFI reports attributable to children in 2017. This is very different (almost the opposite) from the data on the CAEFISS database. While aware that CAEFISS has an active reporting system for about half of all SAE reports for children, this still leaves us asking, why manufacturers capture so few serious AEFI reports for children? Our fractured reporting system certainly contributes to this, since most health professionals report to provincial health departments who in turn report to CAEFISS. Relatively few health professionals or others report to the CV database. Further, a good proportion of reports on the CV database are from published reports that manufacturers are required to scrutinize and report on. This is not reflected in the pie chart. Rather, depending on the occupation of the author of the report these are scattered throughout the pie chart with the other spontaneous reports.

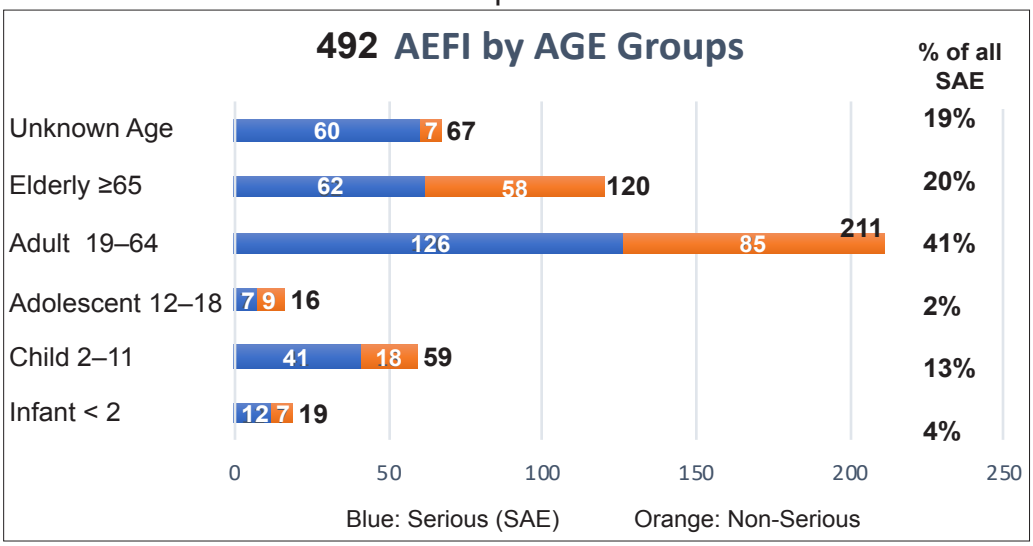
Drug Ineffectiveness/Vaccine Failure

In the report for the first half 2017, we again see (as we did in 2016) that **drug ineffectiveness** is listed as the most common adverse event reported.

We searched the CV database for the 3 vaccines with highest frequency of reports: Influenza, Zostavax (shingles) and Pneumococcal.

Of the 174 AEFI for Influenza, of which 110 were Serious, drug ineffectiveness was not listed. However, vaccine failure was listed twice as were 9 cases of Influenza following vaccination.

For Zostavax there were 18 reports that listed ***drug ineffectiveness***. Also separate from those 18 reports,

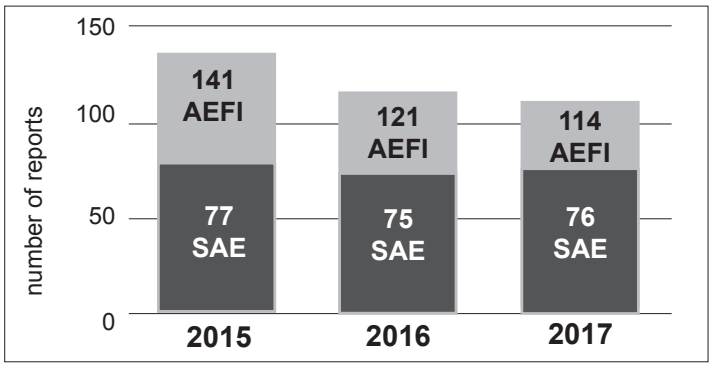


← Total: **308** (62%) of all AEFI reports were Serious. Only **34** (11%) of SAE reports were for children.

All children (18 and under) account for 94 (19%) of 2017 CV AEFI reports. Whereas, 2017 CAEFISS shows 60% of AEFI reports were for children.

there were 17 reports that listed Herpes Zoster (shingles) as an adverse event. Only one of these noted vaccine failure, however all 17 represent either drug ineffectiveness or vaccine failure.

Zostavax 2015–2017: 376 AEFI & 228 SAE reported to Canada Vigilance



Disturbingly there was one case of shingles in a 16 month old female following a Varivax® (chicken pox) inoculation. There were also 6 other reports of varicella (chicken pox) following Varivax® shots, all in children from 15 months old to 10 years old. One report listed 'vaccine breakthrough infection' along with the varicella diagnosis.

Pneumococcal vaccines include Prevnar13® used mostly for babies and Pneumovax23® used mostly for adults. There were 17 **drug ineffectiveness** reports for Prevnar13 used on children, including one infant. Most reports had no age, but the age group was listed. All reports where from physicians. There were 2 reports of vaccine failure for Pneumovax® 23. There were also 4 reports of pneumonia in adults (ages 26–65) following Pneumovax23® vaccination, which may indicate vaccine failure. Of all reports, 8 were from published material.

We searched other vaccines for drug ineffectiveness reports, but found none. However, we did find vaccine failure reports.

There were 3 reports of vaccine failure following Hib (*Haemophilus Influenzae b)* vaccine in infants, due to Haemophilus infection. Reports were from published data, not spontaneous reports to CV.

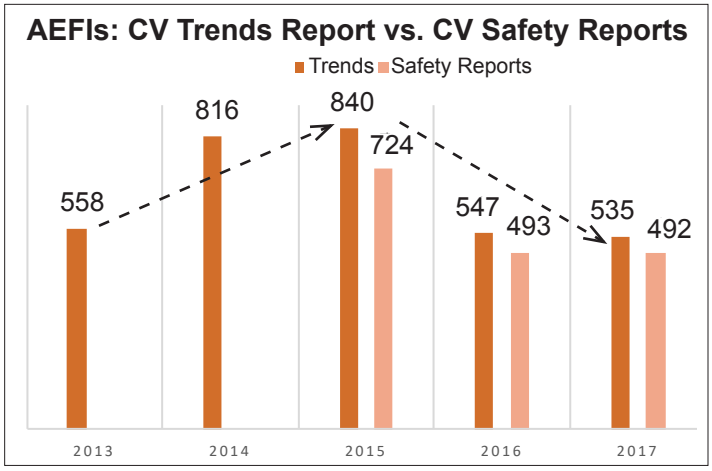
There were 3 reports of vaccine failure for MMR and MMRV vaccines: one for varicella (chicken pox)following Proquad® in an 18 month old. Following MMR®II, one report for mumps (age blocked) and one for measles in a 36 year old. We found no reports of vaccine failure or drug ineffectiveness for DTaP, Meningococcal or Rotavirus vaccines.

While shingles and pneumococcal vaccines account for the majority of drug ineffectiveness/vaccine failure reports in 2017, in total there are 71 listed above that we found in our searches. That means 15% of all AEFI reports to CV in 2017 indicated drug ineffectiveness or vaccine failure, either by directly using those words as an adverse event or listing the disease being vaccinated against as an adverse event.

CV Trends Report: 2013–2017 Vaccine Data

In the Health Canada Trends Report, the number of vaccine adverse events for the last 5 years are found in a series of diagrams in the report. This is the first time we have seen CV vaccine adverse event data for 2013 or 2014, since the published CV Safety Reports only began in 2015. In the chart below, the data is compiled from the Trends Report and compared to the data published in the CV Safety Reports.

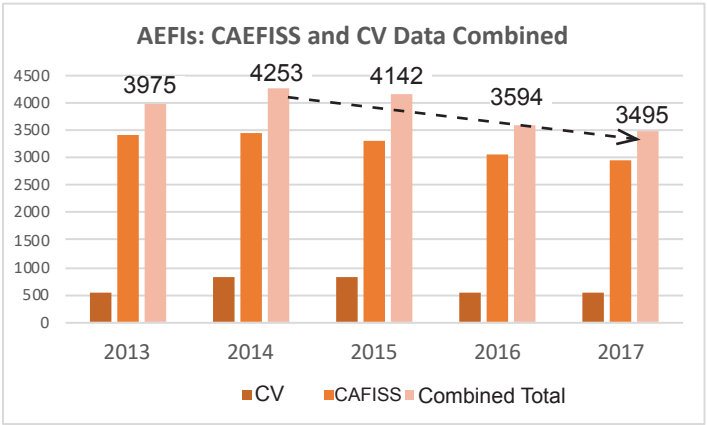
AEFIs: CV Trends Report vs. CV Safety Reports



Similar to CAEFISS, fewer AEFIs are being reported in the CV *Safety Reports* than are held on the CV database according to the *Trends Report*. The total difference between the two reports for 2015–2017 is 213 AEFI reports. The other fact that is clear from the chart is that the number of CV reports declined significantly in 2016 and 2017 compared to 2014 and 2015. The increase from 2013 to 2015 is also evident.

Total AEFI: CAEFISS & CV Data Combined

Using data from the *CV Trends Report* and *CAEFISS 2017 Annual Report*, the total number of AEFI reports over 5 years and the decline since 2014 is shown.



Part 3: 2017 Ontario Vaccine Safety Report Analysis

Ontario Public Health published their 2017 Vaccine Safety Report in November of 2018. It is available as a pdf file here. This 51-page document has a wealth of information for Ontario residents. As we have said numerous times, it could serve as a model of a more thorough and informative report for national level surveillance reporting as opposed to the flawed, 7-page document CAEFISS presented for 2017.

Vaccine Safety Surveillance Tool

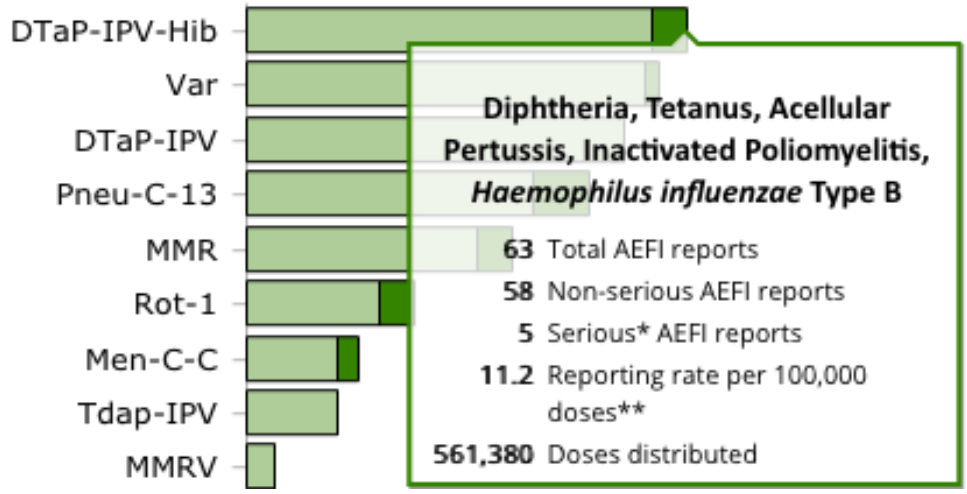
Ontario residents also have access to the interactive, on-line Vaccine Safety Surveillance Tool. We highly recommend parents and other Ontario residents considering vaccines make use of this tool. It is very easy to use and has a lot of information. For example, below are two screen shots comparing the specific vaccine DTaP-IPV-Hib for 2012 and 2017.

At one's fingertips are the total number of AEFI reports, the breakdown for Serious and Non-Serious reports, the reporting rates per 100,000 doses and the number of doses distributed.

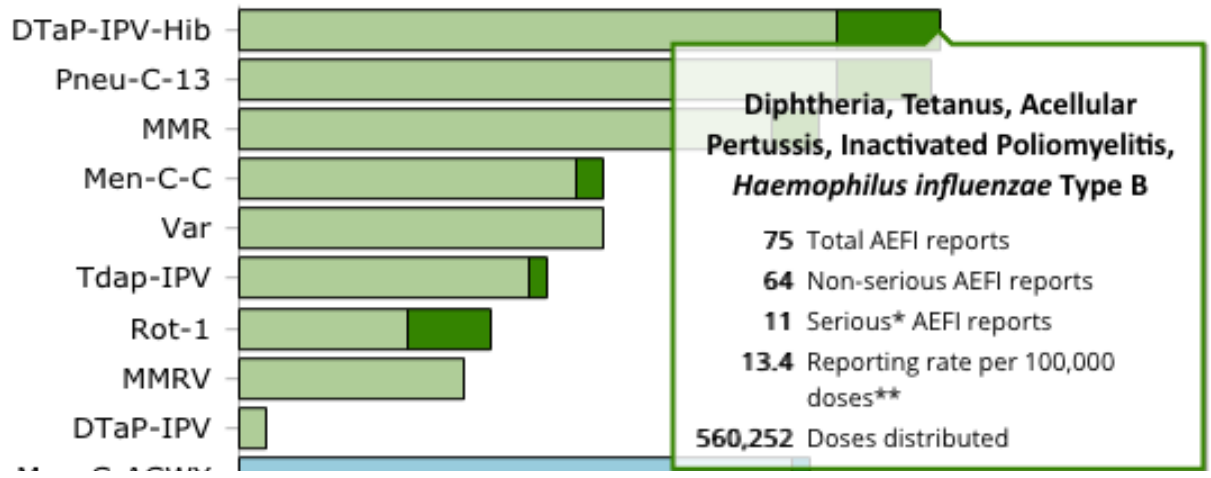
In this example, more than 1000 fewer doses were distributed in 2017 than in 2012, but more reports were filed. So, the reporting rate increased from 11.2 in 2012 to 13.4 in 2017. This vaccine is given at 2, 4, 6 and 18 months of age in Ontario.

In 2017, 75 infants/babies had AEFI reports filed for this vaccine, 11 of which were Serious. This represents only a small portion of infants or babies, who will have experienced **actual** serious adverse events following vaccination with the DTaP-IPV-Hib vaccine.

Number of AEFI reports by vaccine in Ontario, 2012



Number of AEFI reports by vaccine in Ontario, 2017



2012–2017 AEFIs & Reporting Rates

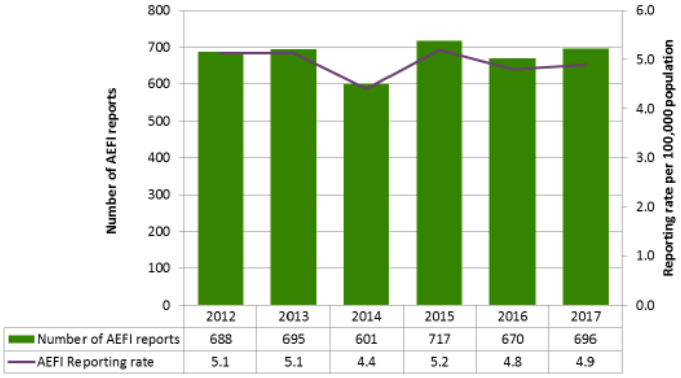
The Ontario Safety Report does not include actual numbers in their graphs and charts, but those numbers are available in the Appendices and with the Vaccine Safety Surveillance Tool.

In the Results section of the report, simple graphics show 6-year annual comparisons and the accompanying text is comprehensive and easy to understand.

For example, the text for Figure 1, which shows the 6-year trend of AEFI reports, explains,

"In Ontario, 696 AEFI reports were received following vaccines administered in 2017, representing a population-based reporting rate of 4.9 per 100,000 population (Figure 1). The annual reporting rate between 2012 and 2017 ranged from 4.4 to 5.2 per 100,000 population…The addition of delayed reports (i.e., reports received in 2017 from vaccines administered in previous years) accounted for <1% increase of the total number of confirmed AEFI reports in 2012 to 2015 and 6.3% increase in 2016, compared to the numbers reported in the 2016 report."

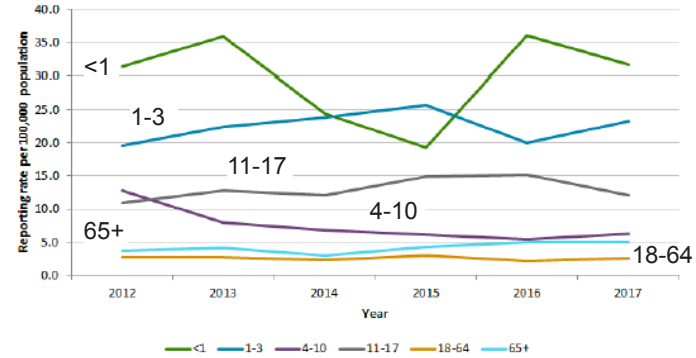
Figure 1. Number of Reports and Reporting Rate of AEFIs per 100,000 Population by Year: Ontario, 2012-17



Age Distribution

Rather than obscuring age group reporting rates as CAEFFIS does, Ontario presents a simple line chart for age group reporting rates first (Figure 2), then follows with a gender distribution chart (Figure 3, not shown).

Figure 2. Annual AEFI Reporting Rate per 100,000 Population by Age Group: Ontario, 2012–17



VCC Note: We have added the age groups to the lines in Figure 2 for easier reading in our report.

It is easy to see that infants, babies and toddlers to 4 years old have the two highest reporting rate, followed by the 11 to17 age group with the third highest rate. The text of the report gives details, of which we note the following:

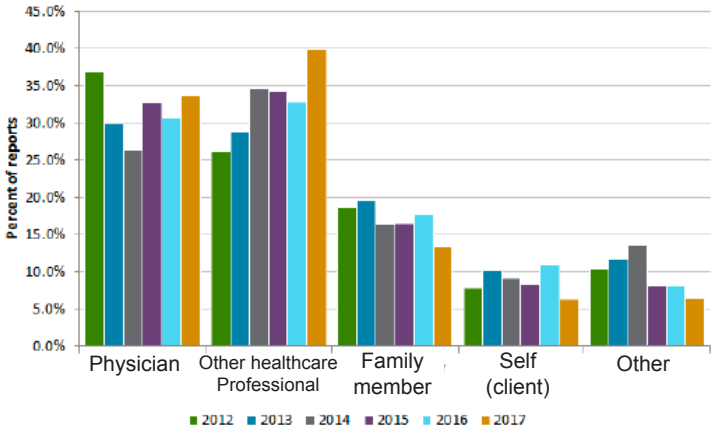
- "half of all reports were among those younger than 18 years of age (49.6% of total AEFI reports)"
- "the highest AEFI reporting rate in 2017 was in infants under one year (31.6 per 100,000 population), followed by children aged one to three years (23.3 per 100,000 population)…"

Reporting Source

The text accompanying Figure 4 is detailed and most informative:

"In 2017, the majority of AEFIs were reported by physicians and other healthcare professionals (73.5%; 458 of 623 reports with reporting source completed)… The proportion of reports received from physicians has fluctuated over the six-year period, whereas the proportion of reports from other healthcare professionals (e.g., nurses, pharmacists) has generally increased since 2012 and exceeded physician reports since 2014. In particular, the proportion of reports from other healthcare professionals increased from 26% in 2012 to 40% of all reports in 2017, representing the largest increase among all categories. Of note, pharmacists started administering influenza vaccines (to adults and children five years of age and older) as part of the universal influenza immunization program (UIIP) in Ontario in 2012."

Figure 4. Percent Distribution of AEFIs by Reporting Source: Ontario, 2012–17



Notes:

- Excludes 382 reports between 2012 and 2017 with unknown reporting source.
- Reporting source 'Other healthcare professional' includes the following iPHIS values: healthcare professionals, hospital, health area, lab and branch office.
- Reporting source 'Other' includes the following iPHIS values: Facility, insurance, other agency, workplace, personnel, friend, detention centre and other (specify).

VCC Note:
We have increased text size for group names in Figure 4 for easier reading in our report.

Geographic Distribution

All Vaccines

This section of the report covers all public health unit (PHU) AEFI reporting. As the report explains,

"There was a wide variation in AEFI reporting by PHU in 2017 with PHU-specific reporting rates ranging from 0.0 to 22.0 per 100,000 population. Twenty-two PHUs (61.1%) met or exceeded the overall provincial AEFI reporting rate of 4.9 per 100,000 population in 2017, while the remainder (14 PHUs) were below the provincial rate, including the three most populated PHUs (Figure 5)."

Much information including maps and graphs on the reporting by the many Public Health Units (PHU) is included in the report and report Appendix. We have omitted these graphics from our discussion, but they are easily accessible for those interested. Suffice it to say that the 3 largest PHUs had low reporting rates. The Appendix 1 table shows these to be:

Peel Region: population 1,507,069, reporting rate of 3.4
Toronto: population 2,952,051, reporting rate 2.5
York Region: population 1,188,629, reporting rate 1.4

We have also omitted the graphics available in the report for the individual PHU reporting rates for the following 3 sections of the report; but quote portions of the text, as follows [emphasis ours]:

Routine Infant and Early Childhood Vaccine Series

"The rate of AEFI reporting for infants and young children (i.e., under four years of age) for the six vaccines that are typically delivered by a primary health care provider as part of the routine infant and early childhood vaccine series (DTaP-IPV-Hib, Rot-1, Pneu-C-13, MMR, Men-C-C, and Var) was determined for each PHU.

"The PHU-specific reporting rates **ranged from zero to 109.0 per 100,000 population and the overall provincial rate was 22.4 per 100,000 population.** There were seven PHUs that reported zero AEFIs among this age group for any of these six vaccines (Figure 6)…"

School-Based Vaccines

"Among 11- to 17-year-olds, the PHU-specific reporting rate for AEFIs following the four vaccines that are administered to adolescents by PHUs in school-based programs (Men-C-ACYW, HB, HPV4 and HPV9) **ranged from zero to 43.6 per 100,000 population, with a provincial rate of 9.7 per 100,000 population.** Twelve PHUs did not report any AEFIs for these three vaccines in this age group in 2017 (Figure 7)…Of note, HPV9 replaced HPV4 in the Grade 7 school-based program for boys and girls in September 2017…"

Influenza Vaccine

"In 2017, 4,037,049 net doses of influenza vaccine were distributed throughout the province…Rates of influenza AEFI reports are calculated per 100,000 doses distributed, both by doses distributed within each PHU and provincially (reporting rates per 100,000 population are available in the online Vaccine Safety Surveillance tool). The overall PHU-specific reporting rates following influenza vaccine **ranged from zero to 30.3 per 100,000 doses distributed, with a provincial rate of 4.1 per 100,000 doses distributed.** Six PHUs did not report any AEFIs following administration of influenza vaccine…"

Suspect Vaccines

The next sections of the report give detailed information on each vaccine and the adverse events associated with the vaccine in AEFI reports. These sections comprise eight pages of the report. This is the information that CAEFISS has decided citizens don't need to know.

On the following pages, we have reproduced small portions of the various tables from three sections: 1)Vaccines, 2)Descriptions of Adverse Events and 3)Serious AEFIs. The reader can then see how comprehensive and transparent this information is.

We also reproduce portions of the text from each section below. Refer to the report for complete tables and discussions.

Vaccines

This section opens with the following information:

"In 2017, there were approximately 8.5 million doses of vaccines distributed in Ontario for the publicly-funded immunization programs. Using net doses distributed for each routine, publicly-funded vaccine as the denominator, the highest vaccine-specific AEFI reporting rates in 2017 were observed for Zos, HPV9 and Men-C-ACWY vaccines (40.4, 35.0, 32.8 per 100,000 doses distributed, respectively; Table 1). Both HPV9 and Men-C-ACWY vaccines are delivered through school-based programs and Zos became a publicly-funded vaccine program for persons between 65 and 70 years old in September 2016…Overall, vaccine-specific serious AEFI reporting rates for all vaccines for which rates could be derived ranged between zero and 3.1 per 100,000 doses distributed. The vaccine-specific serious AEFI reporting rates based on doses distributed were highest for two vaccines given routinely in infancy, Rot-1 and Pneu-C-13 (3.1 and 2.1 per 100,000 doses distributed respectively)."

Adverse Events Descriptions

This interesting information on rashes is contained in the text for this section:

"Rashes were the second most frequently reported specific adverse event-type, present in 22.8% of reports (n=159); 97.5% were classified as non-serious. Among those AEFI reports with rash, 45.3% (n=72) were associated with administration of a live virus vaccines (either MMR, MMRV,

Table 1. Number of Reports of AEFIs and AEFI Reporting Rates per 100,000 Doses Distributed by Vaccine: Ontario, 2017

Vaccine[1]	Number of AEFI Reports	Vaccine-Specific Reporting Rate[2]	Number of Serious Reports	Vaccine-Specific Serious Reporting Rate[2]	Doses Distributed[2]
Infant and childhood vaccines					
DTaP-IPV-Hib	75	13.4	11	2.0	560,252
Pneu-C-13	74	15.4	10	2.1	479,383
Rot-1	27	9.2	9	3.1	294,005
Men-C-C	39	21.7	3	1.7	179,654
MMR	62	20.7	5	1.7	299,968
Var	39	18.6	0	0.0	209,329
MMRV	24	12.5	0	0.0	191,774
DTaP-IPV	3	170.8	0	0.0	1,756
Tdap-IPV	33	14.5	2	0.9	227,264

Var or Zos) and 62.5% (n=45) of these occurred within five to 42 days of vaccine administration (i.e., within the expected range of time to rash onset for live virus vaccines); the remaining 27 reports (37.5%) indicated a rash occurred within four days or less of vaccine administration. Among those occurring within five to 42 days, four were confirmed as vaccine-strain by genotyping, including three that were measles vaccine strain (all following MMR vaccine, one serious - see further description in Serious AEFIs) and one varicella vaccine strain (following varicella vaccine), which was classified as non-serious."

This is important information for two reasons. First, it confirms that almost half of rashes are associated with live virus vaccines and that some are actually vaccine-strain infections. These breakthrough infections are something parents have reported and are concerned about, but that public health officials usually deny.

However more importantly, Ontario properly classifies "rashes" as systemic events. (See page 6, Systemic Reactions in Appendix B (Adverse Events Following Immunization) of the OPHS, Infectious Diseases Protocol, 2015). This classification is also seen in the portion of Table 2, Adverse Event Description on the following page. BC, Alberta and Saskatchewan also classify rashes as systemic events. Note that CAEFISS has created a special category for rashes in Table 1. This minimizes the importance of many rashes as systemic events following vaccination.

As the above quote from the Ontario Report states, 45% of rash reports are associated with administration of four live virus vaccines, three administered to babies and children and one to the elderly.

Table 2. Number and Distribution of AEFI Reports by Adverse Event Category: Ontario, 2017

Adverse Event Category[1]/ Adverse Event[2]	Number of AEFI Reports[3]	Percent of All AEFI Reports (%)[4]	Number of Serious AEFI Reports
Systemic events[1]	251	36.1	12
Adenopathy/lymphadenopathy	13	1.9	3
Arthritis/arthralgia	11	1.6	0
Fever in conjunction with another reportable event	78	11.2	9
Intussusception[3]	2	0.3	2
Parotitis	2	0.3	0
Persistent crying/screaming	6	0.9	2
Rash	159	22.8	4
Severe vomiting/diarrhea	26	3.7	4
Syncope with injury	19	2.7	0

CAEFISS Data vs. Ontario Data

Below is a clip of the data from the 2017 CAEFISS Report Table 1 (page 12) where "Rash alone" is its own category. Beside it is a clip from page 18 of the Ontario Technical Annex that shows' rashes' as Systemic Events with the same 3 sub-categories as CAEFISS.

When CAEFISS records provincial data they must selectively remove the rashes from the Systemic Events to place in their own "rash alone" category.

Of note is that the national CAEFISS Report did not capture the 4 Serious rash reports listed in the Ontario Systemic Events above. CAEFISS shows no reports below in the "% SAE" column for any 'Rash alone' category.

We also note that **CAEFISS did not capture the sudden death reported in Ontario** on the next page. In CAEFISS Table 1 (on page 12) the SIDS/SUDS (deaths) in the "Other" category both say N/A.

We can only ask why these errors occur in the 2017 CAEFISS report and wonder if other provincial statistics have also been recorded inaccurately in the CAEFISS national report for 2017.

CAEFISS 2017, Table 1

Rash alone	Generalized	291	0
	Localized	35	0
	Location not specified/ extent unknown	20	0
	TOTAL	346	0

Ontario Technical Annex 2017, page 18

Systemic events	Rash	Rash	Rash – generalized
			Rash – localized at injection site
			Rash – localized at non-injection site

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Appendix 4: Summary of Serious AEFIs, 2017

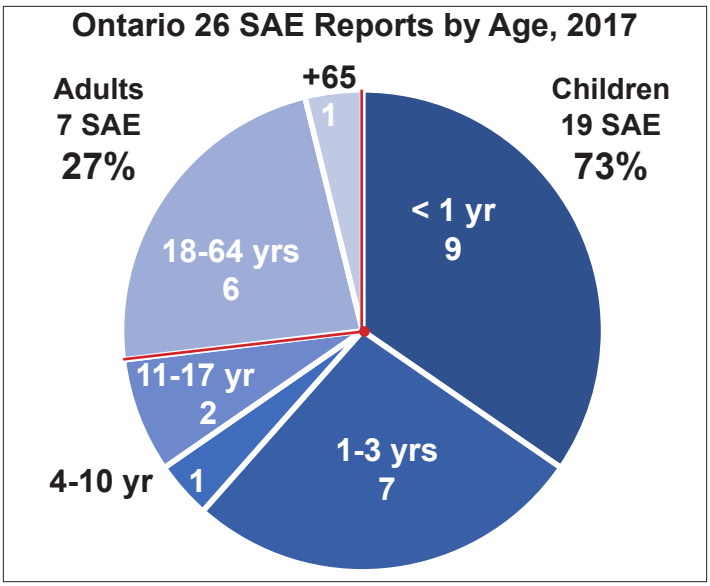
Event-Type[1]	Number of AEFI Reports	Age Group (years)	Associated Vaccines[2]	Additional Information
Febrile illness	8	<1 (n=2) 1-3 (n=5) 18-64 (n=1)	DTaP-IPV-Hib, HA, Inf, Men-B, Men-C-C, MMR, Pneu-C-13, Pneu-P, Rot-1	Three Kawasaki disease (KD) and one each of pneumonia, febrile seizure, seizure vomiting and diarrhea, laboratory-confirmed measles vaccine strain illness, and management of fever requiring hospitalization due to an underlying medical condition.
Local reaction	4	4-10 (n=1) 18-64 (n=2) 65+ (n=1)	HB, Inf, Men-C-ACWY, Pneu-P	Three cellulitis and one infected abscess.
Neurological events	4	11-17 (n=1) 18-64 (n=3)	HPV-9, Inf, Men-C-ACWY, MMR, Tdap-IPV, YF	One each of encephalopathy, aseptic meningitis, acute disseminated encephalomyelitis and transient ischemic attack.
Intussusception	2	<1(n=2)	DTaP-IPV-Hib, Pneu-C-13, Rot-1	-
Respiratory distress	2	<1 (n=2)	DTaP-IPV-Hib, Penu-C-13, Rot-1	-
Seizure	1	<1	DTaP-IPV-Hib, Pneu-C-13, Rot-1	-
GERD/poor oral feeding	1	<1	DTaP-IPV-Hib, Men-B, Pneu-C-13, Rot-1	-
Vaso-occlusive crisis	1	11-17	Men-C-C, MMR, Tdap-IPV	Onset of chest and thigh pain seven days after receiving vaccine.
Persistent vomiting/low hemoglobin	1	<1	DTap-IPV-Hib, Pneu-C-13, Rot-1	-
Henoch-Schonlein Purpura (HSP)	1	1-3	DTap-IPV-Hib, (Tetanus Ig)	Onset of pupura, upper resipratory tract infection symptoms, arthralgia and ear and abdominal pain approximately two weeks after receiving vaccine.
Sudden death	1	1-3	DTap-IPV-Hib	Occurred within 24 hours of receiving routine immunization. Possible natural causes identified on autopsy.

Serious AEFIs

This section begins with the following information:

- *26 AEFI reports in 2017 were classified as serious, representing 3.7% of all reports*
- *25 serious AEFI reports followed administration of at least one publicly-funded vaccine*
- *The majority of serious AEFIs (73.1%; n=19) occurred in individuals under 18 years of age, with most in children under four years (n=16).*
- *25 serious AEFIs in 2017 were admitted to hospital with a mean length of stay of 10 days*

Using the Appendix 4 table above and the report text on Serious AEFIs, we created the pie chart on the next page to show the distribution of 2017 Ontario SAEs by age group.



Low Ontario Reporting Rate

And finally we direct readers to the Discussion section of the report beginning on page 26, which states:

"The provincial AEFI reporting rate increased slightly in 2017 (4.9 per 100,000 population) compared to previously published 2016 data (4.5 per 100,000 population)…

Ontario's AEFI reporting rate has been consistently lower relative to other jurisdictions…As a comparison, the Canadian national AEFI reporting rate was 11.9 per 100,000 doses in 2017 and the Australian annual reporting rate was 12.3 per 100,000 population in 2015.The causes of Ontario's low reporting rate are likely multifactorial, including under-reporting by healthcare providers, which is discussed in further detail in previous reports."

The 2017 CAEFISS Report has different numbers than Ontario uses above.The abstract states:

"The AEFI reporting rate was 12.6/100,000 doses distributed (8.1/100,000 population) in Canada for vaccines administered in 2017..."

Therefore putting the correct data in an easier form for comparison, we see the following:

AEFI Reporting Rates Comparison

	per 100,000 Doses	per 100,000 Population
Ontario 2017	–	4.9
Canada 2017	12.6	8.1
Australia 2015	–	12.3

So Ontario's population-based AEFI reporting rate is 60% of the Canadian national rate and 40% of the Australian national rate. Canada's national rate is about two-thirds of the Australian.

Lower reporting rates indicate many AEFIs are not being reported by those who administer vaccines and/or treat patients who have been vaccine injured.

Almost all stories from the vaccine injured or the parents of the vaccine injured bear this out in that the possibility that a vaccine was the cause of the injury or death is usually immediately denied by the caregiver. It is unlikely these caregivers are reporting these injuries as AEFIs even though all injuries following vaccination should be reported as such.

ISPA and Low Reporting Rates

The low reporting rates in Ontario are especially concerning since Ontario functions under the Immunization of School Pupils Act (ISPA), which is exerting increasing pressure on parents to vaccinate their children despite safety concerns on the part of many parents. Only one other province, New Brunswick, has this type of legislation and parents can just sign a simple form when they register their children for school saying they do not want to vaccinate their children. Not so in Ontario.

Apparently the province sees no reason to increase pressure on healthcare providers who administer vaccines to report AEFIs that result from the ISPA-enforced, childhood vaccination and catch-up vaccination programs.

In fact, Ontario Public Health could easily educate their own public health nurses to increase reporting rates of school-based programs.

And if Public Health Ontario were willing to take a stand on increasing AEFI reporting through doctor's associations, then the infants, babies and young children who bear the brunt of the assault on their maturing immune systems and brains would be taken more seriously by the entire medical establishment and the industry itself.

Part 4: Causality Assessment—Yesterday and Today

Yesterday: Causality Assessment in Canada

This Canadian paper, Monitoring signals for vaccine safety: the assessment of individual adverse event reports by an expert advisory committee, was adopted by and released as a model by WHO in 2000. It contains much information on how the process of AEFI causality assessment works in Canada, and is worth a read for that reason. However, it has little detail about the basis for specific decisions that go on behind closed doors by panels of experts who meet twice a year.

At the time this report was written, between 4,000 to 5,000 AEFI reports were received annually for the five years 1994–1998 covered in the report. The three following tables sum up the assessment process used then. Table 1 lists the number of cases considered for assessment. The committee only assesses the most severe AEFI cases, weeding out the less severe or those **pre-determined** to not be related to vaccines, as this statement attests: *"In addition, some events that meet the severity criteria but are known to be unrelated to immunization, e.g. sudden infant death syndrome (SIDS) or infantile spasms, will also be rejected from detailed review..."*

Table 1. **Review of cases, by selection criteria, for the period 1994–98**

Diagnostic category	No. of cases	No. per year (average)
Anaphylaxis	88	18
Afebrile convulsion — with hospitalization	189	38
Febrile convulsion — hospitalization for >3 days[a]	48	10
Encephalopathy/encephalitis/meningitis	49	10
Anaesthesia/paraesthesia/paralysis	87	17
Guillain–Barré syndrome	18	4
Thrombocytopenia	43	9
Other serious or unusual event — hospitalized	264	52

[a] To distinguish the clinically significant febrile seizures.

Table 1 above shows the 786 reports (approximately 150 reports per year or ~3% of annual AEFIs) that made it through the severity selection process. That is, they were determined to be SAEs worthy of review. These reports (cases) were then run through a series of assessment questions to determine if they would be subject to detailed review with the assessment criteria.

Table 2 lists the WHO (Brighton) criteria. There are 6 categories: Very likely/Certain, Probable, Possible, Unlikely, Unrelated and Unclassifiable.

The causality is based on 1) timing of the event in relation to vaccination (temporal association), 2) whether there were concurrent illness or other drugs/chemicals being administered at the same time, and 3) completeness of information in the report.

Table 2. **WHO causality assessment criteria**

Very likely / Certain	Clinical event with a plausible time relationship to vaccine administration, and which cannot be explained by concurrent disease or other drugs or chemicals
Probable	Clinical event with a reasonable time relationship to vaccine administration, and is unlikely to be attributed to concurrent disease or other drugs or chemicals
Possible	Clinical event with a reasonable time relationship to vaccine administration, but which could also be explained by concurrent disease or other drugs or chemicals
Unlikely	Clinical event whose time relationship to vaccine administration makes a causal connection improbable, but which could plausibly be explained by underlying disease or other drugs or chemicals
Unrelated	Clinical event with an incompatible time relationship to vaccine administration, and which could be explained by underlying disease or other drugs or chemicals
Unclassifiable	Clinical event with insufficient information to permit assessment and identification of the cause

Note the terms 'plausible' or 'reasonable time relationship' are not defined. The definition is up to each jurisdiction using the criteria. The criteria are also open to different interpretations in other ways besides temporal. As an example of how the criteria are interpreted, here is a discussion from the report regarding an event that is *"…thought to be due to the vaccine in the context of the underlying condition. For example, an elderly person with chronic cardiac failure might develop symptoms of cardiac decompensation [worsening of the signs and symptoms of heart failure] after influenza vaccination due to a vaccine-caused elevation in temperature or stress from a local reaction at the site of vaccination. The vaccine is therefore considered to have contributed to cardiac failure in this specific situation only."* In other words, this could be assessed as a probable or possible vaccine-caused event, rather than unlikely due to an underlying illness. There are other examples of criteria interpretation in Section 2 of the report.

Table 3 shows the assessment outcomes for the expert committee reviews that were undertaken.

Table 3. **Outcome of case reviews by causality assessment, 1994–98**

	No. of cases[a]	Proportion (%)
Very likely	31	8.7
Probable	31	8.7
Possible	58	16.3
Unlikely	56	15.7
Unrelated	88	24.7
Unclassifiable	92	25.8

There are a total of 264 cases that were classified with the criteria (less the 92 unclassifiable). This is 34% of the 786 original cases in Table 1. According to the 2006 CAEFISS Report there were a total of 22,463 AEFI reports for 1994–1998. Therefore, 264 assessed cases are 1.2% of all AEFI reports.

Yesterday: CAEFISS Causality Information

The 2006 CAEFISS Report was the last report to provide causality information for the Canadian public. Table 6 from the report shows 502 serious event reports over eight years for which causality assessment reviews were performed. This represents 1.5% of 32,334 AEFIs.

Note: The terms very likely/probable and unlikely/unrelated have been combined and presented as "probably related" and "unlikely related. So we only see three categories in the table with no unclassifiable reports mentioned. 48% of the SAE reports were therefore classified as possibly or probably related to the vaccine administered.

Table 6. ACCA causality assessment for serious AEFI, 1997 to 2004 (n = 502)

	Causality Assessment		
Adverse event	Not likely	Possible	Probable
Anaphylaxis (22)	2	3	17
Thrombocytopenia (61)	19	21	21
Neurological (200)			
- Encephalopathy	7	3	0
- Encephalitis/meningitis	23	3	2
- GBS	14	12	7
- Bell's palsy	11	7	2
- HHE	1	4	6
- Convulsions	53	22	23
Hospitalized ≥ 3 days (90)	54	16	20
Death (20)	16	1	3
Other (109)	61	15	33
VCC Added Totals	261	107	134
	52%	21%	27%

Today, CAEFISS reports only report on causes of deaths, usually with a simple statement that death was due to an underlying medical condition (coincidental).

Yesterday: Causality Assessment in the USA

We searched the literature and found only one 2012 paper that details causality assessments for 100 events from the American VAERS database for one year, 2004. This report is behind a pay wall, but the abstract gives us the following information:

- A stratified random sample contained 13 fatal cases, 19 cases with non-fatal disabilities, 39 other serious non-fatal cases and 29 non-serious cases.
- Modified World Health Organization criteria were used to classify the causal relationship between vaccines and AEFI as definite, probable, possible, unlikely or unrelated.
- Results:
  3% definitely causally related to vaccine received
  20% probably related
  20% possibly related
  53% were classified as either unlikely or unrelated to a vaccine received.
  Note: no mention of other 4% of reports

It is difficult to compare the Canadian and American data since the American data contained both serious and non-serious reports. However, both assessed just over 50% of reports as unlikely/unrelated to vaccines.

Yesterday: Causality in The Netherlands

Much more interesting to us was a 2011 AEFI Report from The Netherlands. This 145-page report covers AEFI reports in 2010 and historical data for comparison from 1994–2009. The entire report is remarkable in its approach to AEFI reporting, beginning with the first statement that openly and statistically addresses the true public concern regarding vaccine safety:

"In 2010, 800,000 children received one or more vaccines on 1.3 million dates, with more than 7 million vaccine components. There is always some chance of adverse reactions but these are usually not severe, though sometimes frightening. This year, RIVM received 1380 reports of adverse events following immunization (AEFI)."

The length of the report is another clue as to the thoroughness of its examination of AEFI reports. The discussion section alone is 30 pages. In that section, many subjects are covered, including vaccine failure and AEFI reports for specific vaccines. These subjects are not even broached in the CAEFISS reports. Here is what the Netherlands Report (page 86) says about **vaccine failure reports, which function as an empirical measure of vaccine efficacy**:

"Vaccine failures have traditionally been reported to RIVM through the telephone service or by notification through the RIVM (related) microbiological labs. These events raise a lot of questions and concerns regarding the efficacy of the vaccine and about programmatic errors as well.…Sometimes the vaccine failure points to possible vaccine or administration related problems, sometimes to underlying immune disorders, requiring different actions. These reports must be regarded as adverse events, but it has not been easy to have them accepted as such by the national medicine registration board."

So the resistance to reporting vaccine failure is duly noted. This resistance is certainly evidenced in Canada today where this subject is not discussed in the CAEFISS

reports. Many CV database reports show the disease being vaccinated against as an adverse event, but fail to use the adverse event terms 'vaccine failure' or 'drug ineffectiveness'.

However, the main subject of our comments here is the approach to vaccines as a cause of AEFI reports. Numerous sections of The Netherlands report are devoted to Causality Assessment.

The general discussion states, *"Causality assessment has been a routine part of the safety surveillance since the start in 1962. This rating has inextricable consequences for future vaccinations, both for the individual and for the population."*

This acknowledges that causality assessment affects vaccine program policy decisions as well as individual vaccine decisions. No doubt this is why such assessments are no longer part of routine, national public reporting in Canada.

They explain criteria interpretations thus: *"As a rule, we use 'unlikely' as code for coincidental events following vaccination and 'no relation' only if it concerns inverse chronology (event before vaccination) or if a definite proof of a different cause has been established. Even then, however, these cases are included in any cumulative or aggregated analysis, and all cases are reassessed regularly against new scientific evidence or new signals."*

They end this general discussion with this statement: *"We include in our aggregated analysis and annual reports all reported adverse events for transparency, with inclusion of causality assessment since this is more informing than a non-assessed list of reported events…"*

Of course, transparency is of little concern to our public health authorities, so all we see are non-assessed AEFI lists, ones that may or may not include all reported adverse events (as noted earlier).

The detailed information on causality is contained in three pages (Section 4.5 Causal Relation) of the report with tables, charts and discussion on vaccine causality for both 2010 and the previous six years covered by the report. Note they assess **all** AEFI reports for causality. Events assessed as certain, probable or possible are considered adverse reactions to vaccines (ARs).

Results: In 2010, 78% of reports were considered adverse reactions, with exclusion of 2 non-classifiable events. Range for 2004-2009 is 72-83%.

Below is Table 10 showing the frequency of reports classified as ARs by causality assessment. They do not use the serious/non-serious classifications of reports, rather they use the terms 'major' and 'minor'. Approximately 48% of the reports are what we classify as serious adverse events (SAEs) in Canada as they note in the Abstract: *"Reported adverse events in 2010, 78% of reports (1082) had possible causal relation with the vaccination. These concerned major adverse reactions in 48% (523), including very high fever (>40.5 °C), persistent screaming, collapse, discoloured legs, febrile convulsions or atypical attacks chills, myoclonics or hyper/hypo-tonicity."*

Table 10 Causality and events for AEFI reports in 2010 with proportion AR

event ⇓ causality⇒	certain- probable-possible	improbable	non classifiable	total	% AR*
local reaction	320	1	-	321	100
general illness minor	296	156	1	452	65
major	53	47	-	101	53
persistent screaming	51	2	-	53	96
skin symptoms	58	41	1	100	58
discoloured legs	96	2	-	98	98
faints	154	10	-	164	94
fits	54	31	-	85	64
anaphylactic shock	-	-	-	-	-
encephalopathy/-itis	-	-	-	-	-
death	-	5	-	5	0
total 2009	1082	296	2	1380	78

* = percentage of reports considered adverse reactions (causality certain, probable, possible) excluding non-classifiable events

Total of 1380 AEFIs, all assessed for causality:
78% (1082) were certain, probable, or possible
21% (296) were improbable (coincidential)
<1% (2) unclassifiable

The Netherlands has a special department for child vaccine surveillance that is staffed with knowledgeable clerks who take phone-in reports. They attempt to speak to more than one person and target parents for eyewitness accounts of the event: *"In 2010, we had information from others than the reporter in 85% of cases. A detailed account from the parents was received in 92%. The GP supplied information for 144 (10%) reported adverse events and from the hospital we received information in 227 (20%) cases."* The majority of reports (70+%) are submitted by staff from the state-run child vaccine clinics.

They have this to say about written reports versus phone reports: *"A check on completeness of information of these written reports, over the last few years showed that their quality was actually poorer and more inaccurate. More reports were anonymous, contained faulty birth dates and wrong vaccination dates et cetera. To track down additional information took generally more effort and time and was often unsuccessful. Comparison is hampered because phone reports are complemented and clarified in the reporting phone call, a feature not possible in written reports."*

The diligence of collecting data as described here is in sharp contrast to how the Canadian and American surveillance systems operate. No wonder there is so much missing data in Canadian AEFI reports.

The report also discusses each vaccine and the

overall reporting rates and AEFI numbers as they relate to changes in the Vaccine Schedule.

The Netherlands childhood schedule in 2010 was much less rigourous than either the Canadian or American schedules for 2010 with fewer vaccines, optional choices, and later time lines for some vaccines.

Age	Vaccine		
birth	HepB0[a]		
2 months	DTP-IPV-Hib1(-HepB[b])	+	Pneu 1
3 months	DTP-IPV-Hib2(-HepB[b])	+	Pneu 2
4 months	DTP-IPV-Hib3(-HepB[b])	+	Pneu 3
11 months	DTP-IPV-Hib4(-HepB[b])	+	Pneu 4
14 months	MMR1	+	MenC
4 years	DTP-IPV5		
9 years	DT-IPV6	+	MMR2
12-13 years	HPV dose 1,2,3	girls only	

[a] = for children born from HepB carrier mothers

[b] = for extended risk group of infants with parent(s) from middle of high endemic HepB countries.

VCC Note: 'DTP' is a DTaP, not a whole cell vaccine (phased out in 2005)

In the schedule, there are no Rotavirus or early MenC for infants, no Varicella, 2nd MMR not given until 9 years of age and no 4-valent MenC-ACYW or HepB booster for adolescents in contrast to the Canadian schedule at that time.

So with fewer vaccines and a more spread out schedule one could reasonably expect The Netherlands has fewer AEFI reports for children than either Canada or the USA does.

The upshot is that for the 7 years covered in this report with all 8,612 AEFIs received assessed for causality between 72% and 83% of the reports were considered certain, probable, or possible to be related to the vaccines given. The certain, probable and possible causality mathematical means are also given for 17 years:

1994-2004: 82% (DPT phased out after 2004)

2005-2009: 76% and 2010: 78%

For all of the reasons discussed above, we consider the 76%–78% range to be a much more reliable positive causality assessment rate for all AEFI reports than that derived from either the Canadian or American data that was less inclusive, had smaller samples over shorter time periods and found 47% to 48% of reports were certainly, probably or possibly related to vaccines.

Above all, we laud The Netherlands for their obvious concern for children's health and parental concerns in their report gathering and causality assessment process.

Today: WHO Revised Causality Assessment Criteria

The World Health Organization (WHO) released these new criteria in 2013. They were essentially written to bring undeveloped nations onboard for causality assessment. However they were not an immediate success due to the confusing language and algorithms presented. They have been revised with the final release in January of 2018 of the 2nd Edition, which we address here with the official citation requirement and a link to the pdf:

Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification (Second edition). Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.

Here is their own description of the new process:

"In 2013 the WHO developed a revised methodology for the causality assessment of an AEFI. This new methodology incorporates a four-step process including (1) an eligibility component that reviews the diagnosis associated with the event, identifies the administered vaccines and creates a working hypothesis; (2) a checklist that systematically guides users to collate available information; (3) a decision support algorithm that assists the assessors to arrive at trends in classification; and (4) the final classification of the individual AEFI. "

Essentially what these revised guidelines establish is a business model for reducing the number of AEFI reports on a global basis, rather than a medical/biological model for protecting children from vaccine damage. This is made abundantly clear by an extensive critique of the revised WHO causality guidelines that was published in May of 2018 by Drs. Jacob Puliyel and Pathik Naik, both practising pediatricians in India. These men are known for the many papers they have published advocating for children's health with safer vaccines and transparent reporting of AEFIs. (Link to 181 papers and comments on PubMed by Dr. Puliyel)

Below is the Abstract from their detailed Critique on the WHO causality guidelines. It contains the doctors' two main concerns. There are many others and many examples presented in the full document.

"The World Health Organization (WHO) has recently revised how adverse events after immunization (AEFI) are classified. Only reactions that have previously been acknowledged in epidemiological studies to be caused by the vaccine are classified as a vaccine-product–related-reaction. Deaths observed during post-marketing surveillance are not considered as 'consistent with causal association with vaccine', if there was no statistically significant increase in

deaths recorded during the small Phase 3 trials that preceded it. Of course, vaccines noted to have caused a significant increase in deaths in the control-trials stage would probably not be licensed. After licensure, deaths and all new serious adverse reactions are labelled as 'coincidental deaths/ events' or 'unclassifiable', and the association with vaccine is not acknowledged. The resulting paradox is evident.

The definition of causal association has also been changed. It is now used only if there is 'no other factor intervening in the processes'. Therefore, if a child with an underlying congenital heart disease (other factor), develops fever and cardiac decompensation after vaccination, the cardiac failure would not be considered causally related to the vaccine. The Global Advisory Committee on Vaccine Safety has documented many deaths in children with pre-existing heart disease after they were administered the pentavalent vaccine. The WHO now advises precautions when vaccinating such children. This has reduced the risk of death. Using the new definition of causal association, this relationship would not be acknowledged and lives would be put at risk. In view of the above, it is necessary that the AEFI manual be revaluated and revised urgently. ***AEFI reporting is said to be for vaccine safety. Child safety (safety of children) rather than vaccine safety (safety for vaccines) needs to be the emphasis."***

While shocking, we find this assessment to the point. For those interested in the negative impact on AEFI causality assessment, both the WHO Revised Guidelines and the Critique should be read in full as we can only present selected information here.

In our estimation, the most important parts of the WHO manual and the Critique concern the algorithm, An algorithm is defined as a procedure for solving a problem, based on conducting a sequence of specified actions. The Algorithm in the WHO manual exposes the attempt to remove many AEFIs from the record as Puliyel states above.

We present below the revised Algorithm. We have added the manual comments (grey boxes) to the graphic for better understanding of what is being shown. This is followed by the Critique comments on the various numbered questions posed in the Algorithm flow chart and a simplified flow chart of the Algorithm from the Critique.

WHO Manual Algorithm

The reviewer of an AEFI will first have determined if the report is eligible for causality assessment (Step 1). If not (due to lack of information or a valid case definition or temporal association), it is not assessed. If it meets eligibility the Checklist questions will be asked (Step 2). Then the AEFI will have its causality assessment applied (Step 3). This is the step that uses the algorism below.

The four central boxes (I,II,III & IV with the red arrows) are the Checklist questions that lead to one of four AEFI causality classifications: Consistant with causal association, Inconsistant with causal association, Indeterminante or Unclassifiable.

Fig. 3. Causality assessment algorithm

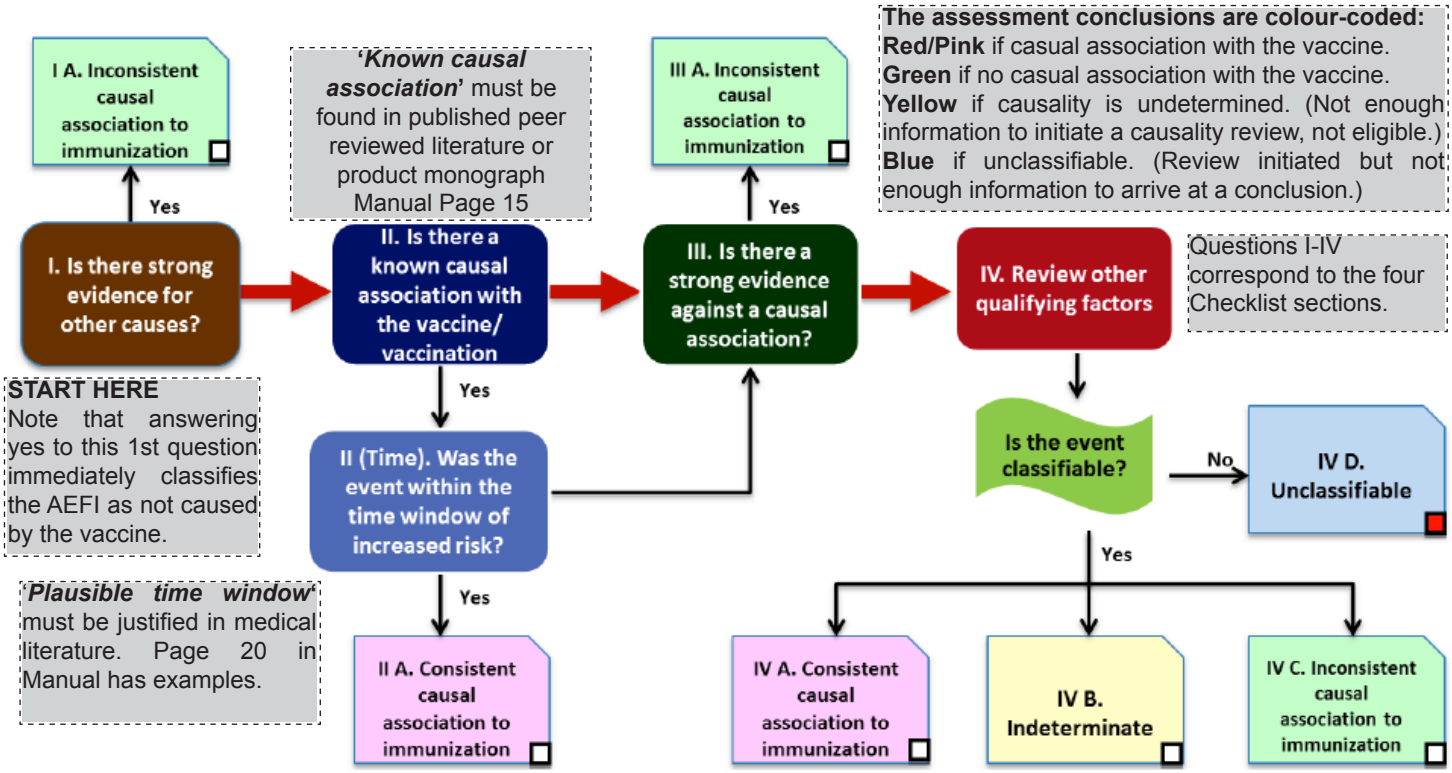
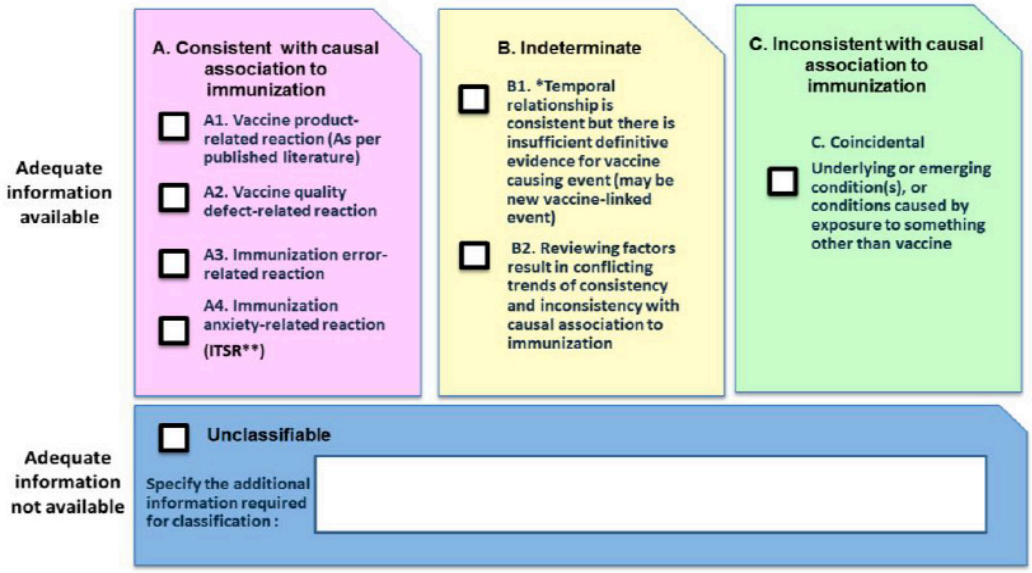


Figure 4 (manual page 25) clarifies the Algorithm classifications. See manual pages 28-31 for discussions.

Note in A (pink) there are four reasons a vaccine could be found to cause an adverse event. Only A1 declares the vaccine accountable for the adverse event. A2 & A3 relate to staff handling (ie, lack of temperature control) and vaccine administration errors by vaccinators (wrong vaccine administered or off license use) and A4 to patient fault. Our concern with A4 is that classifying a physiological reaction (shock, fainting, low blood pressure, hyperventilation, myoclonic jerks, etc.) as **only** a transitory, psychological, anxiety-related adverse event, cements the industry myth that shock responses to HPV vaccines are not related to the vaccine itself.

The Critique speaks to B2 where an event can be categorized as both consistent or inconsistent with vaccine causality! As to C, nowhere does the algorithm acknowledge that vaccines can trigger adverse events when underlying conditions are present. If there is an underlying condition, there is no vaccine causality.

Fig 4. Causality assessment classification



Below we present extended excerpts from the Critque: Puliyel J and Naik P. Revised World Health Organization (WHO)'s causality assessment of adverse events following immunization—a critique [version 2; referees: 2 approved]. F1000Research 2018, 7:243 (https://doi.org/10.12688/f1000research.13694.2) For ease of reading we have not italicized the long excerptss. They are in quotation marks only.

CRITIQUE of the WHO Manual Algorithm

Step I Other Causes

"The first step in the revised algorithm is to look for strong evidence for other causes. If there is an alternate explanation, the AEFI is classified as 'Inconsistent with causal association to immunization'. John Mackie has noted that in nature there could be multiple reasons (causes) for the same outcome, and if two possible causes exist simultaneously either of them could be the causative factor[8]. It is to be noted that with the WHO-UMC classification of ADR and the old WHO/Brighton Classification of AEFI, even if an alternate explanation is available, a causative association with drug or vaccine is still considered 'Possible'. Moreover, the two causes could be working synergistically. An example of this is where genetic and other individual susceptibility factors make one susceptible to developing an AEFI[15,16]. In the new algorithm, if there is an alternate explanation for the AEFI, or another factor is involved, causative association with vaccine is rejected[12,14]."

Step II Known Casual Association

"The CIOMS/WHO Report on pharmacovigilance is used at this level[13]. AEFI-specific case definitions for some reactions have been developed. In instances where specific case definitions and criteria are not available for a particular AEFI, it is permissible to improvise using case definitions adopted from 'standard medical literature, or national guidelines or they may be adopted locally by the reviewers' (page 11 CIOMS /WHO report). AEFI that meet case definitions and which occur within the time window of increased risk are classified as 'consistent causal association to immunization'.

"The acceptable time window for each adverse event is different. The macrophagic myofasciitis affected patients usually are middle-aged adults presenting diffuse arthromyalgias, chronic fatigue, and marked cognitive deficits, fatigue, or depression due to long-term persistence of aluminium hydroxide within macrophages at the site of previous immunization[17]. However, AEFI surveillance seldom extends for so long."

Step III Evidence Against Casual Association

"Theoretically, reactions that are not known to have a causal association or those that are not in the time window of increased risk can move to Step 3. At this stage, an enquiry is made whether there is strong evidence against causal association. Proving of a negative is notoriously difficult as it is impossible to affirm that in every circumstance, an irregular outcome is impossible. The example provided in the manual relates to MMR and autism.

"It is reported that the Global Advisory Committee on Vaccine Safety (GACVS) and Council for International Organizations of Medical Sciences (CIOMS) committee have concluded that no evidence exists of a causal association between MMR vaccine and autistic disorders. Such AEFI must be classified as 'inconsistent with causal association to immunization' according to the new algorithm.

"After publication of this AEFI user's manual, the conclusion about MMR and autism have become disputed again (see Box 3). [Box 3 cites CDC whistle blower Dr. W. W. Thompson, the study and media reports.] This shifting evidence calls into question the usefulness of introducing this step in the algorithm of AEFI."

Step IV Is this a Classifiable Event

"Assuming that no such 'strong evidence against a causal association' exists, reactions that are not known to have a causal association with the vaccine, can go to Step 4. It is from here that reactions may be classified as indeterminate allowing it to be evaluated in future as a new signal.

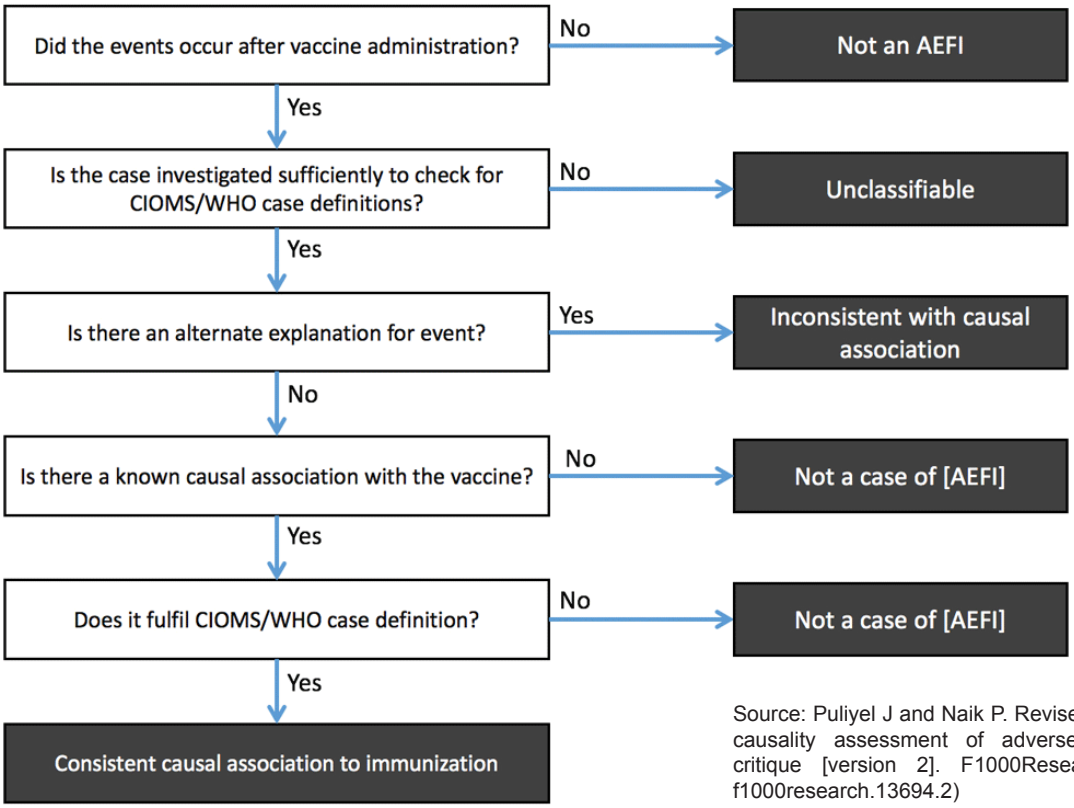
"The question at this point is whether it is 'classifiable —meaning whether all the tests needed have been performed to allow it to be classified under the CIOMS/WHO definitions. This is the second time these definitions are invoked during the AEFI evaluation.

"If some investigations are not done or not available, the AEFI is labelled as 'Unclassifiable' (or classified as 'Inconsistent with causal association to immunization' like how flaccid paralysis following OPV was classified, because investigations during an illness 1 month prior to paralysis were not available — see Appendix 3, page 36 [page 42 in 2nd Edition] of the AEFI manual[12] for this example).

"If all the required investigations had been done and they met case definition criteria, they would have been classified as 'consistent causal association to immunization' at Step 2 and would not have come to Step 4.

"The third possibility is that all the investigations had been done so it is classifiable, but it did not meet case definitions. The CIOMS/WHO dictum is applied here: 'if there is adequate evidence that an event does not meet a case definition, such an event should be rejected and should be reported as "Not a case of [AEFI]". (See CIOMS/WHO Definitions and Application of Terms for Vaccine Pharmacovigilance, page 17013). It removes any chance that AEFI that has not been recognized as causatively associated with immunization in previous epidemiological studies will be included in the 'Indeterminate' group and evaluated as a new signal. Thus there seems to be only two options at Step 4: either the reaction is classified as 'Unclassifiable' or it is categorized as 'Inconsistent causal association to immunization'. Categorization as 'Indeterminate' or 'Consistent causal association to immunization' are logically impossible given the riders mentioned above.

"The exercise does not end there. Other qualifying factors are also enquired into at Step 4. It is recommended that alternate explanations in terms of background rate, other health conditions, exposure to a potential risk factor or toxin, acute illness, and other medication are again enquired into. Many of these 'other qualifying factors', like prior illness and concurrent drug use would presumably have been eliminated at Step 1 when looking for evidence for other causes. This enquiry is repeated again at Step 4 quite unnecessarily. Box 4 illustrates how, in spite of there being epidemiological evidence (the TOKEN Study) that pentavalent vaccine can cause sudden unexpected death, the numerous deaths (as discussed in the introduction) are not acknowledged as caused by the vaccine, and the WHO expert report denies that deaths were ever reported as AEFI. The causality assessment of 132 serious AEFI cases uploaded on the website of the Ministry of Health and Family Welfare in India illustrates the consequence of deploying this new classification. 54 of these babies died, whereas 78 survived. The causality assessment found 50% of those who survived had reactions to vaccination but not even one death was classified as vaccine-related. Nearly all the deaths (96%) were simply classified as unclassifiable or coincidental, presumably because death has not previously been acknowledged as an adverse event caused by this vaccine[18]. Children admitted to hospital after vaccination with intractable convulsions, could be classified as having a vaccine-product related reaction, but if they died, the deaths would be classified as 'coincidental deaths'."



Source: Puliyel J and Naik P. Revised World Health Organization (WHO)'s causality assessment of adverse events following immunization—a critique [version 2]. F1000Research 2018, 7:243 (doi: 10.12688/f1000research.13694.2)

VCC Comment: In a separate section of the Critique the figure above is presented. It is a reconfiguration of the WHO Algorithm into a simple and understandable format. The text that accompanies it is titled, **"Revised AEFI classification and the precautionary principles".** It states:

"It is evident from the discussion earlier that the revised AEFI evaluation scheme produced by the CIOMS/WHO is designed to deny the possibility that any newly observed adverse event may be causally related to the immunization. The AEFI manual states *'Allegations that vaccines/vaccination cause adverse events must be dealt with rapidly and effectively. Failure to do so can undermine confidence in a vaccine and ultimately have dramatic consequences for immunization coverage…'*[12]

"Figure 2 shows how all cases [of] AEFI except those that are known adverse effects of vaccine are classified as not causally related.

"The AEFI-denialism is a clear violation of the 'precautionary principle' (European Union law), which mandates that 'when an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. Society and Government is urged that until the full scientific evidence is available, where there is evidence of risk, it must take precautionary measures'. This new AEFI classification scheme that allows for an outright denial of any new causative association with vaccination could also fall foul of Article 2 European Convention on Human Rights (Art 2 ECHR), which mandates governments to establish a framework of laws, precautions, and means the enforcement of which will, to the greatest extent reasonably practicable, protect life.

"Paradoxically, the AEFI algorithm is said to be for vaccine safety. Perhaps we need a scheme for public safety rather than vaccine safety.

"The story of pentavalent vaccine was introduced at the beginning of this paper and is summarized in Box 10. It is primarily a vaccine used in developing countries where AEFI surveillance is poor, the press is less vigilant to report adverse events and where drug regulation is less strict. (The richer countries in the West, Europe and the USA, do not use the whole cell pertussis vaccine; so this vaccine is not marketed in those countries.) Isolated cases of unexplained deaths continue to be reported in the press. With the new AEFI classification, in the absence of 'epidemiological evidence' linking deaths to the vaccine, these deaths have been passed off as 'coincidental' SIDS deaths. Epidemiological evidence, however, is now available linking the deaths to vaccine."

VCC Comment: While we have hardly done justice to this excellent Critique and urge reads to reveiw it themselves, we will add one more section of the document. This section discusses why the Brighton

classifications were revised and what the 'aftermath' will be:

The need for revising Brighton

"The revised classification have removed the categories 'probably' and 'possible' from the AEFI classification —very much like the experts who investigated the Sri Lanka deaths. This appears to be motivated by a laudable desire to reduce vaccine hesitancy and the attendant risk of vaccine preventable disease. The Sri Lanka report says, *"Cases were classified in this review as unlikely where, in spite of not having evidence that the vaccine(s) contributed to the adverse event or the outcome of death, conclusive evidence regarding an alternate cause (or causes) of the event and outcome was lacking. This meant that we considered that classifying the AEFI in the category 'unrelated' was not fully justified (as it could not be conclusively attributed to another cause). In such cases, we go further to state that the conclusion of 'unlikely' means that the vaccine is not the major cause of death even in those cases where we discuss the possibility that the vaccine(s) or vaccination may have unmasked an underlying condition"*

"It seems the Sri Lankan experts were reluctant, even to classify the deaths as 'unlikely', as it could be interpreted to mean there was some likelihood of causal association. To quote from the report, *"Unlikely: In defining this category, the panel took note of the fact that the WHO category 'unlikely' is often interpreted to mean that there is (conversely) some likelihood of a causal association between the adverse event and the vaccine(s) administered."*

"One can speculate that [the] same reasoning and the motivation (to allay public anxiety of a causal association between AEFI and vaccination), would have provided the impetus for the revised AEFI classification.

The aftermath

"That vaccines do more good than harm is taken as an article of faith, a dogma, a tenet. If the purpose of this exercise in AEFI-denialism is to prevent undermining confidence in vaccines, the scheme does not seem to be working. Indeed, public scepticism seems to be increasing rather than diminishing with these efforts at reassurance that vaccines are safe[25,26]"

VCC Conclusions

We can only concur with these comments. We see the same thing happening in Ontario where the ISPA legislation for school children is postured as being a 'mandate' and significant pressure is exerted on parents and children who attempt to protect their conscience/religious freedoms of informed consent to medical procedures. This coercion combined with knowledge of AEFIs has resulted in a fresh crop of citizens who are questioning voluntary vaccination and have diminishing trust in public health regulation of and reporting on vaccine safety. And this is not happening only under the circumstances that are on-going in Ontario.

Over the last 75 years of childhood vaccination programs in Canada, the number of parents who have held their damaged children in their arms is vast and continues to grow. These parents know what happened to their children. They and their family members will always know as they care for and mourn their damaged and their lost.

Denying that vaccinations could have caused this death and injury—by physicians and their professional associations, by public health employees who administer vaccines and by the entire Public Health bureaucracy from the Provincial to the Federal level—has further undermined public trust.

The Canadian public deserves recognition of their right to informed consent, which includes the right to information and also to refusal of medical procedures of any kind that they may deem as too great a risk.

Instead of scapegoating concerned parents, what needs to be addressed are five things:

1) Deficiencies in our Canadian surveillance systems.
2) Establishment of new guidelines for true, evidence-based safety testing of vaccines.
3) Application of newer, evidence-based, peer reviewed science on the plausible biological connections between vaccines and AEFIs.
4) Training of medical professionals on the relationships of vaccines to various injuries and diseases and the importance of reporting (not denying) these AEFIs.
5) Institution a national Vaccine Injury Compensation Program.

If the above were to be addressed, this would necessarily lead to a reassessment of the current vaccination schedules, the policy decisions that led to them and the burden of injury they place on children in particular and on the public at large.

Vaccine safety is indeed a case of "Honesty versus Policy" as Dr. Humphries states. And "AEFI-denialism" as Dr. Puliyel calls it, will ultimately prove to be a lost cause. As are all such schemes that are not based on compassion, truth and the constantly unfolding complexities of the natural world that scientists continue to reveal.