VACCINE CHOICE CANADA
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Database Update Report:

An analysis of available data

July 2015, By Nelle Maxey

Part 1: Canada Vigilance (CV) Database — Q1 2015 Update

Is the CV database of any use to those seeking public information on vaccine adverse events?

Part 2: CAEFISS Database — Q4 2014 Update

CAEFISS data showed an almost 10% increase in the proportion of serious adverse event reports in 2014 compared to the previous 3 years.

Part 3: 2013 National Immunization Coverage Survey

Has the Canadian public recognized the safety and efficacy concerns of vaccines as coverage rates for children under 2 years of age drop significantly compared to 2011 data?

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Part 1: CV Database Q1 2015 Update

The Canada Vigilance Database has been updated to include the first quarter of 2015 data.

Sorting the database by date (Jan 1 through March 31, 2015) for reports related to vaccines, 38 adverse event reports (AERs) come up for Q1 2015. 19 of these reports are serious adverse event reports (SAEs) or 50% of the total.

The information published with the database (Caveat, Item 5) tells the public:

> "**This database contains only a small proportion of adverse reactions reported following receipt of vaccines, and is reflective of serious reactions reported to market authorization holders** as required under the Food and Drugs Act. The majority of reports of these reaction are submitted to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)."

Despite this characterization of the CV database, it has not been correct since 2011 when a reporting rule change was instituted by Health Canada. As discussed in the original CV Database Report, the rule change stated that vaccine manufacturers/distributors (Market Authorization Holders or MAHs) would **only** report to the CV database instead of the CAEFISS database as they had in the past. Indeed in the 2012 CAEFISS report, PHAC reported a 10% drop in MAH reports on that database. The caveat has not been changed to inform the public of the changing nature of the data on the CV database. Furthermore, other reporters (e.g. doctors, pharmacists, the public) have also been encouraged to report to the CV database, further changing the character of the database. Nor does our analysis show that the reporting rule change has been enforced.

Percent MAH Reports on CV Database

Year	#All AER	#MAH	%	#SAE	#MAH	%
2011	94	70	75%	53	42	79%
2012	67	49	86%	51	45	88%
2013	82	47	57%	50	35	70%
2014	187	116	62%	93	64	69%

The above chart (adapted from the original CV Database report) shows that in 2011 79% of Serious reports were from MAHs, while by 2014 the reporting rate of MAHs had dropped to 69%.

Following up with this analysis for the first quarter of 2015 update, Table A shows the number and per cent of MAH reported AERs and SAEs (serious reports) for the first quarter of the years 2011 through 2015.

Table A: Percent MAH Reports on CV Database for Q1 2011—2015

Year	#All AER	#MAH	%	#SAE	#MAH	%	#NonMAH	
Q1 2015	38	15	40%	19	12	63%	7	37%
Q1 2014	47	23	44%	26	16	62%	10	38%
Q1 2013	9	5	56%	7	4	57%	3	43%
Q1 2012	18	15	83%	15	13	87%	2	13%
Q1 2011	32	26	81%	21	18	86%	3	14%

One would expect the rate (per cent) of MAH reports on the CV database to continue increasing as it decreases on the CAEFISS database due to that rule change on reporting. However, again, this is not the case.

The per cent of both AER and SAE reports from MAHs is overall decreasing on the CV database.

- The per cent of all Adverse Event Reports from MAHs decreased from 81% in 2011 to 40% in 2015.
- The per cent of Serious Adverse Event from MAHs decreased from 86% in 2011 to 63% in 2015.

Another change in the character of the database is that the per cent of Serious Reports compared to All reports on the database is also dwindling over time.

Table B: Percent SAE Reports on CV Database for Q1 2011—2015

Year	#All AER	#SAE	%SAE
Q1 2015	38	19	50%
Q1 2014	47	26	55%
Q1 2013	9	7	78%
Q1 2012	18	15	88%
Q1 2011	32	21	81%

The per cent of all Serious Adverse Event Reports from all sources decreased from a high of 88% in Q1 2012 to a low of 50% in Q1 2015. The public user of this database would have no way of discerning these trends.

The Canada Vigilance Database, the only one the public has online access to, is becoming just **a handful of odd-lot reports rather than a database which is useful for understanding vaccine-related serious adverse event profiles.** (See Example of Use on Page 7.) This prompts two questions: Is this Health Canada's intention? and Whose interests does this database serve?

Part 2: CAEFISS Q4 2014 Update

The CAEFISS 2014 Quarterly Q4 report is available on the PHAC website here. It is difficult to make reasonable comparisons by quarter or annually to other years on the database for the following reason as explained in the Q4 report introduction [emphasis added]:

> "The lower reporting totals for Q4 in 2014 relative to previous years continues a trend seen in previous quarters of 2014. The cumulative total for the entire year of 2014 was **2408** reports compared to an average of **3519** for prior years (range 3167-4012). **The main reason for the drop in 2014 was delayed report transmission from one or more provinces and territories to the Agency, for technical reasons related to implementing a new electronic AEFI reporting system.** While reports have not yet been received by the Agency, they are reviewed and analyzed in the reporting jurisdictions and any concerns communicated via the Vaccine Vigilance Working Group. There were none noted in 2014 and it is expected that the reports will be sent in the first or second quarter of 2015."

Hopefully when the reports are received they will be allocated to the proper quarters and year in the report charts, so in the future reporting trends will be more apparent and annual reporting rates (per cents) can be judged.

The one thing which can be noted with no equivocation is that even though the total number of AEFI reports is down more than 1000 reports compared to previous years average, the total number of Serious AEFI is comparable to other years. **This means the proportion of Serious AEFIs compared to all AEFI reports increased in 2014.** As the report explains:

> "A total of 67 AEFI reports received by the Agency in Q4 of 2014 were serious (**9.7% of all AEFI reports**). During the same periods for 2011, 2012 and 2013, the Agency received an average of 57 (range: 38-75) serious AEFI reports representing from **5.7-6.2% of all AEFI reports** received in the same quarter for these years. The cumulative total of 224 serious reports for all of 2014 was very similar to the average yearly count of 220 serious reports for 2011 – 2013 (range: 186-255)." [Even though some provinces have not yet reported.]

Note what is not presented in this statement is a per cent of Serious Reports to Total Reports for the cumulative totals (that is the annual data, not just Q4 data). It is compiled here from the data above:

Annual	#AER	#SAE	% Serious
2011–2013 Avg.	3,519	220	6.25%
2014	2,408	224	9.3%

This shows a significant **increase** in the proportion of serious adverse events following immunization for 2014.

WHO IS AFFECTED?

Another troubling comparison in the report concerns the annual data on the per cent of serious adverse events **by age group** as presented in Table 2 in the report (shown below). Remember 2014 numbers will likely increase when all the 2014 data is in, but we already see an increase of Serious events for younger children.

Starting at the bottom of Table 2, in 2014 infants under 1 year of age experienced **35% of all Serious Adverse Events**. This is up from **30%** for the previous 3 years. Next (adding bottom 2 age groups, we see that all babies under 2 years of age experienced **61% of all serious events**, up from **54%** in previous 3 years. And finally if we add up the bottom 3 age groups we see that young children, toddlers and infants (all aged less than 7 years old) experienced **72.5% of all serious adverse events** following immunization in 2014 compared to **70.5%** on average in the previous 3 years.

These statistics make perfect sense when you consider the vaccine schedule. 42 doses of 14 vaccines are recommended in the first 2 years of life during critical development phases of the brain and immune system and thus can precipitate injuries leading to neurological and immunological disorders.

Also the IMPACT reporting system which contributes to the CAEFISS database along with Provincial/Territorial (P/T) public health systems is an active reporting system

Table 2: Cumulative serious and non-serious AEFI reports from Jan 1st to end of 4th Quarter, stratified by age group.

Age Group	Serious Adverse Events (SAE)		Non-serious Adverse Events (non-SAE)	
	2014	**Average for 2011-2013**	**2014**	**Average for 2011-2013**
	#, (% total)	**#. (% total)**	**#, (% total)**	**#, (% total)**
Unknown	3 (1.3)	2 (0.9)	23 (1.1)	81 (2.5)
65+ years	11 (4.91)	18 (8.2)	229 (10.5)	279 (8.5)
18-<65 years	31 (13.8)	26 (11.8)	780 (35.7)	1008 (30.6)
7-<18 years	16 (7.1)	20 (9.1)	388 (17.8)	446 (13.5)
2-<7 years	26 (11.6)	25 (11.4)	270 (10.5)	445 (13.5)
1-<2 years	59 (26.1)	69 (31.4)	230 (10.5)	579 (17.6)
0-<1 year	78 (34.8)	61 (27.7)	264 (12.1)	460 (13.9)

in pediatric hospitals. IMPACT reports as many serious adverse reactions in children as all the combined spontaneous reports for adults and children from the Provincial/Territorial health authorities.

WHAT VACCINES ARE INVOLVED?

The most common vaccines identified in all AEFI reports were shown in the Q4 Report in Figure 3 below. The figure is very difficult to interpret as it combines both All AEFI and Serious reports with no numbers on the data columns.

For greater understanding of data, we have broken Figure 3 into two figures shown on the next page. Figure A shows all AEFI reports and Figure B shows Serious Reports only. We have grouped the vaccines types in our figures. The first grouping includes all the Diptheria, Tetanus, Pertussis vaccines. The second is the Pneumoncoccal vaccines. The third is the Measles, mumps, rubella vaccines. Then 4-year averages were calculated and ranked for quick comparisons of the vaccines with the most reports. The profile of vaccines noted in reports is quite different for All reports and Serious reports as our Table C to the right shows.

Of the vaccines listed in Table C, that is those noted in the largest number of reports, it is important to consider not only the nature of the vaccine but the age at which it is administered. The PHAC chart Routine Schedule for Infant and Childhood Immunizations gives this information for each province and territory (P/T). The age administered has been added to Table C. It is readily apparent that adverse events experienced largely by infants/babies after routine vaccinations are what Figures A & B show the highest numbers for.

Table C: Vaccine Type 4-year Averages & Rankings by Number of Reports

Vaccine Type	4-year Averages				Age given
	All AEFI		Serious SAE		All P/T (unless noted)
	# Reports	Rank	# Reports	Rank	
Influenza	805	1	43	4	> 6 months
Pneumococcal C	460	2	88	1	2,4,6 months
Meningococcal C	382	3	61	2	2/4 mths or 1yr*
DTap-IPV-Hib	332	4	49	3	2,4,6,18 months**
Rota	235	n/a	32	5	2,4 months
All MMR & V	194	5	31	6	1 year

*Men C is given at 2 or 4 months in four P/T; the others give at 1 year.
Three P/T give 3 DTap-HB**-IPV-Hib and only 1 DTap-IPV-Hib.

Also note in Figure B, the Rotavirus vaccine (Rota) has seen a **large increase in serious reports in 2014** (47 compared to 17 previous 3-year average). This is especially significant as only it and HB are showing an increase in 2014 Serious Reports over other years even though the 2014 data is incomplete to date. This increase of Rota Serious reports is investigated (and dismissed) in the last section of the 2014 Quarterly Report which you can read on-line. See also our discussion of Rotavirus on page 7 in the **Example of use** of the Canadian databases.

Figure 3: Most common vaccines identified in AEFIs reported from January 1st to end pf 4th Quarter 2014 vs. average for 2011-2013.

(From the Q4 2014 Quarterly Report)

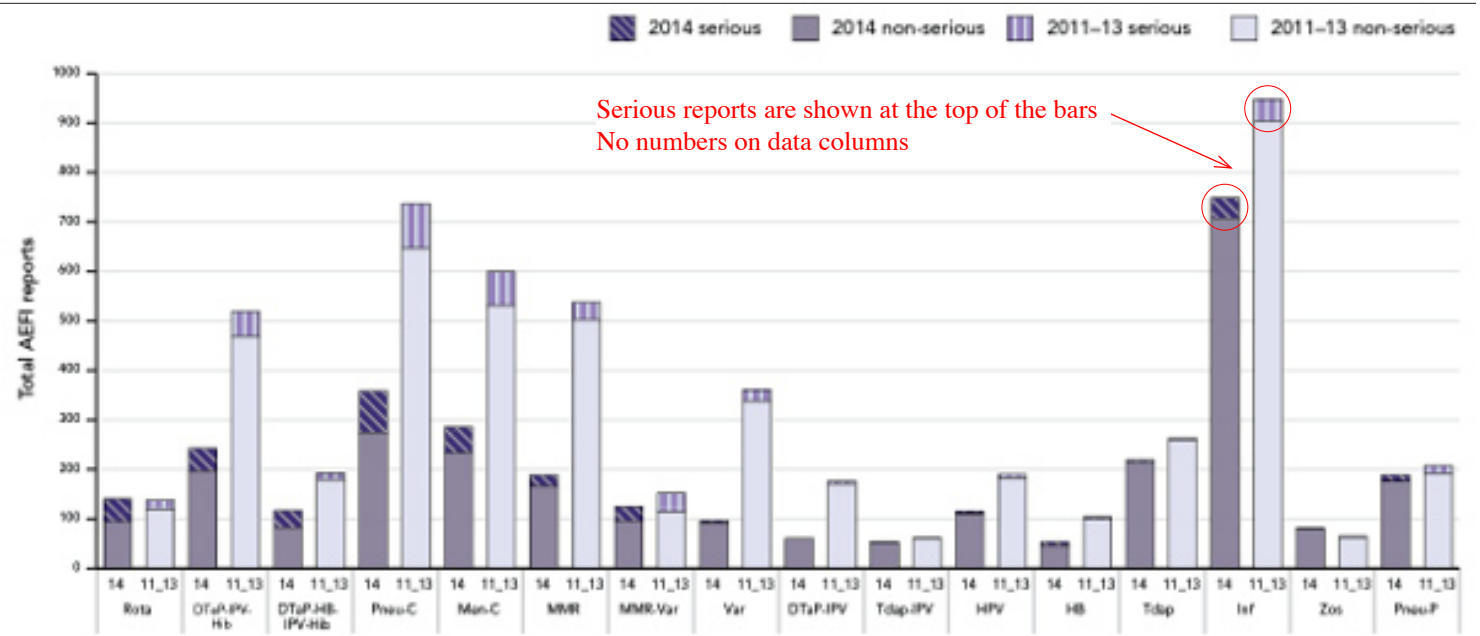


Figure A: Most Common Vaccines Identified in AEFI Reports

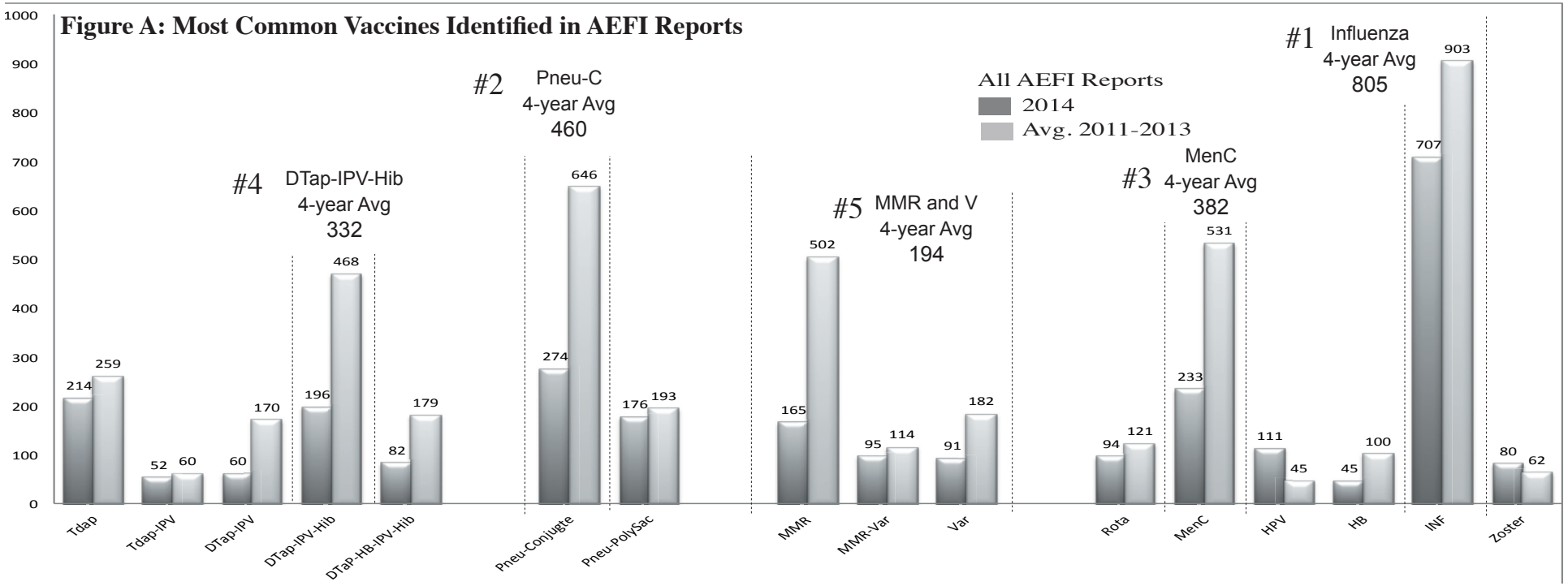
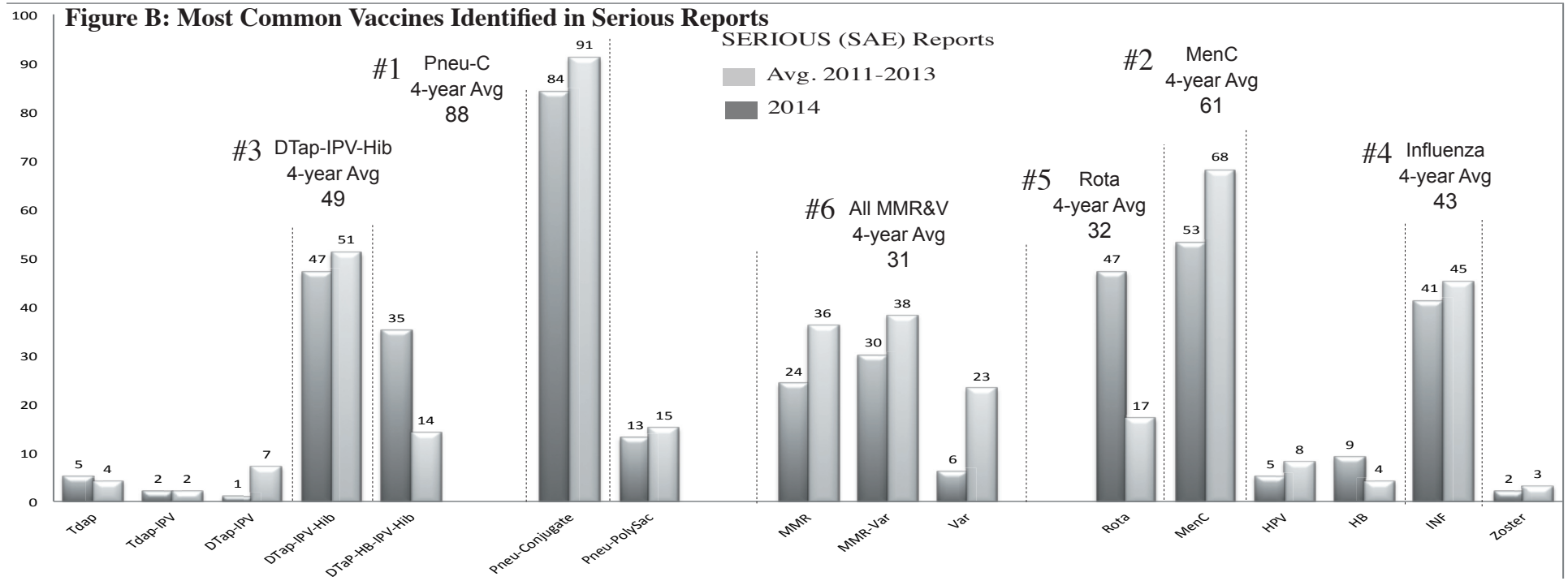


Figure B: Most Common Vaccines Identified in Serious Reports



WHAT SERIOUS ADVERSE EVENTS OCCUR?

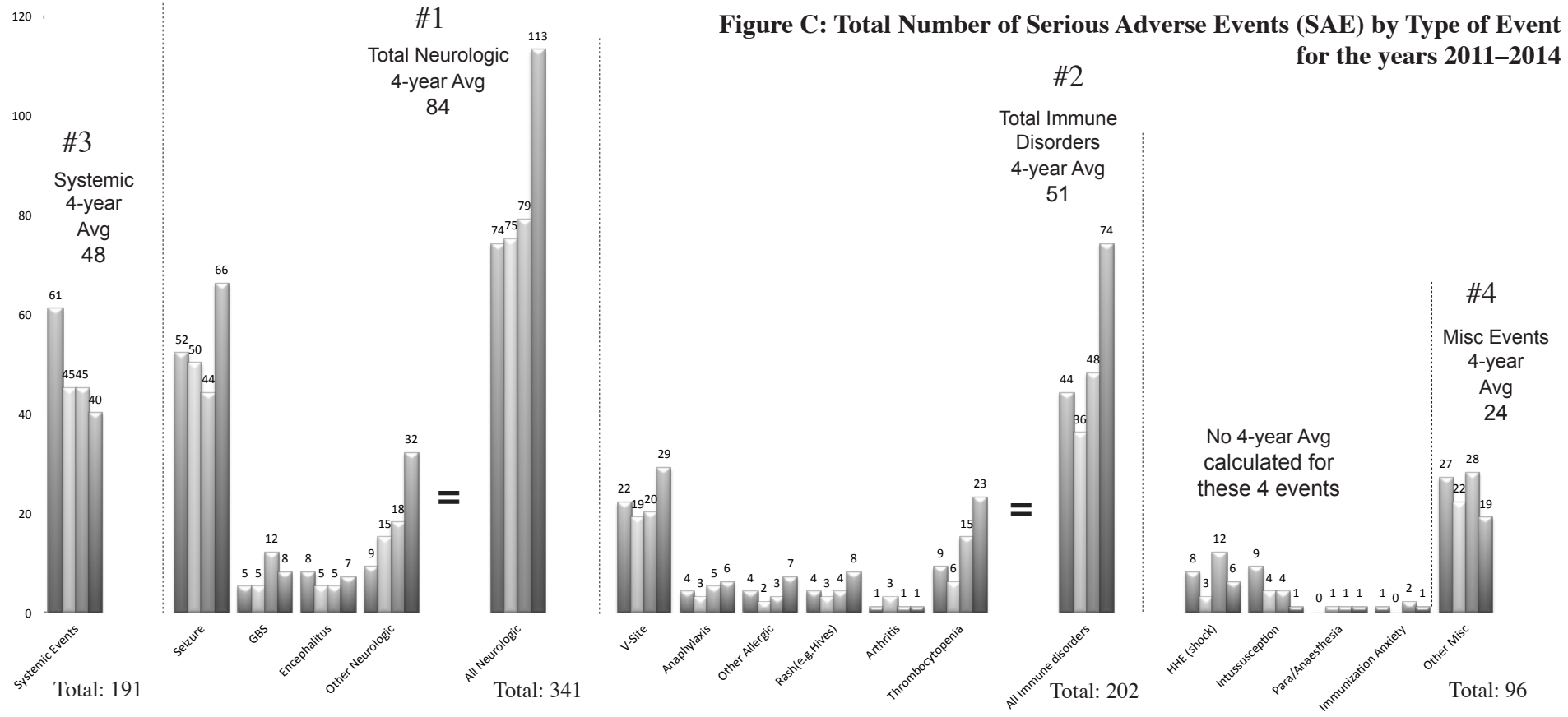
Figure C below, configured from Table 5 in the PHAC Report, shows the **types of events** contained in the Serious Reports for the last 4 years. The columns are presented in desending yearly order: 1st column in each event type is 2014, next is 2013, and so forth. The adverse events have also been loosely grouped for better comprehension of neurologic events and immune system events which are calculated from all events in those 2 groups as indicated by the = signs. **Neurologic events are the most commonly reported type of serious adverse event, followed by Immune disorders.**

The first and last type of events in Figure C—Systemic events and Miscellaneous events—are defined as follows in the PHAC Report:

- **Systemic events:** these are primarily events involving many body systems often accompanied by fever. Any recognized syndromes are classified as systemic events and include such illnesses as Kawasaki syndrome, Steven-Johnson syndrome, Henoch-Schonlein purpura, fibromyalgia and serum sickness. In addition evidence for infection of one or more body parts (respiratory infection, bladder infection, etc.) are included in this category as are instances of rash that is non-allergic in origin and is accompanied by other signs and symptoms such as fever, cough and conjunctivitis. General symptoms such as fatigue, malaise, lethargy, headache, myalgias including influenza-like illnesses are classified as systemic events. Finally fever as the only adverse event reported is included in this category.
- **Miscellaneous other events**: all other adverse events that don't fit into any of the above categories are captured as miscellaneous events. These may be further categorized by the predominant body system they fall under such as gastrointestinal, cardiac, genitourinary, etc.

Some Systemic events or Miscellaneous events could fall into the Immune or Neurologic event groups (for example, serum sickness and fibromyalgia). This is why the groupings in Figure C are said to be *loose*.

Figure C: Total Number of Serious Adverse Events (SAE) by Type of Event for the years 2011–2014



Using Databases to Access Vaccine Safety Profiles

Rotavirus Example: As a parent you want to know how many serious adverse events occurred following Rotavirus immunizations in 2014 in Canada.

1. Canada Vifilance (CV) Database: A Canadian parent's first option in looking for adverse event data for a vaccine is to check the CV database because they have on-line access. Only Rotatrix® is listed on the database at this time, with only 1 report for 2014, which was a Serious event. No vaccine-related deaths are recorded. The individual reports can be read to see what the adverse events were, the age of the patient, the outcomes including deaths and so on. However this database has only *selected* reports as discussed in Part 1 of this VCC report.

2. CAEFISS (Canadian Adverse Events Following Immunization Surveilance System) Reports—Q4 2014: If the parent is aware of the various CAEFISS reports and can find them on the internet, they will see in 2014 there were a total of 94 adverse event reports related to Rotavirus vaccines of which 47 were Serious. CAEFISS reports do not normally report death statistics related to vaccines, nor can the parent read individual reports to determine the vaccine used, ages, outcomes, etc. since they have no access to the actual database. They must be content with the amorphous charts presented in the Quarterly Reports.

3. American VAERS Database: The truly knowledgeable Canadian parent will know they can search the much more comprehensive American VAERS database where they can sort by many more criteria and read all reports. Since the Canadian population is about 1/10th of the American and we have similar vaccination schedules, one can intelligently extrapolate what the expected Canadian data would be.

A search of VAERS based on infants age under one year old for the year 2014 for all rotavirus vaccines resulted in a total of 425 Serious SAEs in 2014. Rotateq® had 244 SAEs, Rotatrix® had 179 and 11 reports failed to name the brand of vaccine. There were 35 vaccine-related deaths: 14 associated with Rotatrix® and 21 associated with RotaTeq®). Extrapolating from this data we would expect to see 3 to 4 deaths and around 43 SAE's Canada.

Reults of Database searches: 2014 SAE reports for rotavirus vaccines

Database	Vaccine brand	#SAE	Event type	Death
Canadian Vigilance	Rotateq	1	can be accessed	0
CAEFISS Q4 Rpt	Rotateq/Rotarix	47	N/A	N/A
VAERS	**Totals**	**425**	can be accessed	**35**
	Rotateq	244		21
	Rotatrix	179		14
	No name listed	11		0

In summary, the CV database is of little use to a parent in determining the number of serious adverse events (or all adverse event reports for that matter). In general, the CAEFISS reports are more useful in determining the number of adverse events related to a particular vaccine, though not the nature of these events. The quality of the data and the access to that data on the two Canadian databases falls far short of that available on the VAERS database.

As a special case, the Q4 2014 CAEFISS report has a special section on rotavirus vaccines (as mentioned earlier). Table 7 is presented in that section which gives the types of events reported for AEFI and SAE reports. This is a unique chance for parents to see this information.

Table 7: Classification, seriousness and reporting rates of adverse events following immunization with rotavirus vaccine based on reports received by PHAC from January 1st, 2011 through December 31st, 2014.

Primary Reason for Reporting	Total AEFI Reports	Reporting rate/100,000 doses distributed	% one vaccine	Total Serious Reports (% all AEFI)
Vaccination site reaction	27	1.30	3.7%	0
Anaphylaxis	7	0.31	28.6%	1 (14.3%)
Other Allergic event	22	1.1	18.2%	0
Seizure	18	0.9	0	13 (72.2%)
Other neurologic event	6	0.3	0	5 (83.3%)
Intussusception	19	0.9	36.8%	16 (84.2%)
Haematochezia	23	1.1	26.1%	2 (8.7%)
Other gastrointestinal event	121	6.0	22.3%	4 (3.3%)
Kawasaki syndrome	8	0.4	0	8 (100%)
Other systemic event	100	4.9	10%	26 (26%)
Hypotonic hyporesponsive episode	36	1.8	5.6%	14 (38.9%)
Persistent crying	19	0.9	26.3%	0
Rash alone	128	6.3	5.5%	1 (0.8%)
Other event not listed above	20	1.0	5%	9 (45%)
Vaccination error with no adverse event	1	0.05	0	0
Total	**555**	**27.5**	**13%**	**99 (17.8)**

Rotavirus vaccines, given at 2 months and again 4 months of age, are included in most publicly-funded routine infant immunization programs in Canada. Both vaccines used in Canada are oral, attenuated live virus vaccines. RotaTeq ®(Merck) is a pentavalent vaccine which contains 5 live viruses from human and bovine sources. Rotatrix®(GSK) is a monovalent vaccine from human sources, after use viral shedding occurs. Product monographs hyperlinked: Rotateq and Rotatrix Parents are encourgaed to access the Vaccine Choice Canada website pages on Rotavirus vaccines for background information and links. We also encourage parents to use the excellent *Vaccine Safety Manual* available for purchase at our online bookstore or at your favorite bookseller.

Part 3: National Immunization Coverage Survey (NICS) 2013

Every two years PHAC releases data on a National Immunization Coverage Survey. In the past there have been 2 surveys, one for children under 17 years of age (cNICS)*and one for adults (aNICS).

The press release in July of 2015 covers "highlights" of the 2013 children survey only. A full report is to follow, "sometime later in 2015". The full set of questions asked in the survey can be seen on-line. Reading these gives a better idea of what the survey was about and how much interesting information was collected.

Actually little hard data on coverage was available in the press release. Most of the press release is about survey methodology, vaccines covered and parent attitudes toward vaccinations.

Hard Data

There is one sentence which states"over all age groups", children who have never received any vaccinations was 1.5%, a significantly small per cent of Canadian children, which one would not expect to "interfere" with "herd immunity". This is reported as 1% in the 2011 report, so a slight increase in unvaccinated children.

Another section states that "almost three quarters of girls between the ages of 13 and 14 were immunized against HPV" and that by age 17 "almost 90% of children were immunized against Hepatitis B".

The other hard data released relates to the per cent of babies at 2 years of age who are **fully immunized** with routine vaccines covered under provincial and territorial publicly-funded programs. The StatsCan chart (pdf) with all this data is available at the hyperlink.

The 2013 data in released StatsCan chart has been compiled in the Comparison Chart here along with the data from the 2011 cNICS report. As the chart makes readily apparent, coverage rates have fallen for all vaccines except the two newest ones at the bottom of the chart—meningococcal C and Pneumococcal C.

It will be interesting to see if this is discussed in the final report. It certainly wasn't in the press release covering "highlights" of the survey.

It is also very important to remember that the chart only shows **fully vaccinated** 2-year old babies. Since many of the childhood vaccinations are multi-dose regimes, some babies could have some vaccine doses but not all, and therefore not appear on the chart. Or their parents may have opted out of a specfic vaccine, or they are not able to be vacinated due to various medical conditions.

As an example, if 77% of babies have been fully vaccinated against pertussis (whooping cough), the other 23% could have been been partially vaccinated against this disease with up to three of the four doses called for in the schedule or not vaccinated at all. While partial vaccination reduces effectiveness of the vaccine, it does not wipe it out entirely, especially in the short time span of 2 years.

Comparison Chart
2011 & 2013 Immunization Coverage for 2 year old Children

Disease	2011	2013	Difference
Diptheria	87.9%	77.4%	-10.5%
Pertussis	87.9%	77%	-10.9%
Tetanus	87.9%	77%	-10.9%
Polio (IPV)	96.2%	91.1%	-5.1%
Hib	87.9%	72.7%	-15.2%
Measles	95.2%	89.6%	-5.6%
Mumps	95.2%	89.2%	-5%
Rubella	95.2%	89.2%	-6%
Varicella (chicken pox)	88.6%	73.1%	-15.5%
Meningococcal C	80.5%	88.6%	+8%
Pneumococcal	76.5%	79.3%	+3.2%

The other information in the press release concerns parent responses to questions about their attitude and knowledge in regard to immunization.

95% of parents thought that childhood vaccines are, in general, safe; and 97% thought they were effective. However 70% of parents are concerned about "the side effects" (a gentler term for adverse events following immunization) and "over a third wrongly believe that a vaccine can cause the same disease it was meant to prevent", says the press release. However it is a known fact that live vaccines like MMR can indeed induce measles in the vaccine recipient and that the virus can be spread to others for a period of time after vaccination through viral shedding. So those "over a third" of parents are not necessarily wrong.

Vaccine Choice Canada will be requesting a copy of all the answers to all the questions in the survey. And we certainly are eagerly awaiting the full report when it becomes available.

* Override the certificate warning to download the 2011 cNICS report or contactVCC.