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

Vaccine Safety Report

VACCINE CHOICE CANADA
FORMERLY VRAN

An analysis of data & databases available to the Canadian Public

By Nelle Maxey for Vaccine Choice Canada, March 2016

Underlined text in this pdf is hyperlinked to references.

The hyperlinked pdf of the Vaccine Safety Report is available on our website main menu at About Vaccines/General Issues/Reports.

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Background

Purpose: Public concern regarding the safety of vaccines has been ongoing for many, many years. Yet there is very little knowledge among the Canadian public or within Canadian media about the reporting and tracking systems for adverse events following vaccination in our country. In an attempt to broaden public understanding, we undertook investigation of the systems.

This is the third Vaccine Choice Canada investigative report on Canada's surveillance of and reportage on vaccine-related adverse events. The investigations were undertaken by a member of the public attempting to find relevant vaccine-related information within the complexities of our government's massive health bureaucracies. The report is written so other members of the public understand the challenges within the systems that have been developed to date and the complexities of various vaccine-related information. Further we hope the medical establishment will utilize the reports to understand where their systems are failing the public interest.

Methods: The on-line Canada Vigilance (CV) database is purported to allow public searches for vaccine-related adverse reactions. We have undertaken many searches of that database in an attempt to evaluate the quantity and quality of adverse reaction reports contained therein. The adverse events data from the other system, CAEFISS, is also analyzed and compared (when possible) to CV data. We have found that understanding what is being reported is complex and inter-related to other information. We have used Health Canada and its agencies' websites extensively to understand the processes, and policies that make data available for public scrutiny. We have interacted with relevant Health Canada agencies through both email and phone conversations to better understand search techniques, reporting pathways, and interactions between the two database agencies. When specific vaccines are noted by either of the surveillance systems as having large quantities of adverse event reports (or fatalities), we have investigated those vaccines. We have used the American VAERS database as a background comparator for specific and overall adverse events reporting. We site sources of both industry-sponsored and independent researchers to substantiate our concerns or to offer better solutions. We compare our vaccine-related information systems to American and European systems in terms of the quality of information available, not just on suspected vaccine injuries but also on disease incidence, vaccine coverage, number and cost of vaccines administered and other information that is necessary for a public attempting to make informed decisions on medical risk taking.

Conclusions:
In the first report (*What the Public Sees, April 2015*), we learned there are two separate databases used to track suspected vaccine injuries in Canada: the Canada Vigilance (CV) database and the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). **We concluded that maintaining two databases is both confusing and wasteful and suggested the databases be combined and made publicly available on-line.**

In the second report (*Update Report, Summer 2015*), we analyzed the latest data from both databases. We also included a special report on **vaccine coverage** statistics for babies and reported on the decrease in vaccine coverage when compared to the previous released coverage data, **concluding that vaccination coverage rates are declining significantly in Canada.** This of course relates to the current push to increase coverage rates by whatever means the government and the industry can devise.

In this third report, the ***Vaccine Safety Report***, we examine the newly established Quarterly Safety Reviews for the CV database. The recent release of these first ever, very brief quarterly reports revealed that all of our previous CV data extractions were completely erroneous, as the CV database does not actually allow for public searches of all vaccine-related adverse reactions, nor even for all reactions related to a specific vaccine or group of vaccines. We also question why reports on the CAEFFIS database have been declining for 10 years while reports on VAERS are increasing. **We conclude that adverse events are being significantly under reported in Canada at a rate closer to 1% of actual events, then the 10% reporting rate claimed for the Canadian databases.** We also compare and contrast certain information from the United Kingdom and Switzerland to Canadian information. **We conclude that Canada's public information related to vaccine safety is barely useful in making informed vaccine decisions, and we offer some solutions for the public and for the medical establishment.**

Some Acronyms used in this report:

AE Adverse event **AR** Adverse reaction
AEFI Adverse event following immunization
CAEFISS Canadian Adverse Events Following Immunization Surveillance System
CV Canadian Vigilance Program (on-line database of AR reports)
VAERS Vaccine Adverse Events Reporting System (the American database)

SAE Serious Adverse Event following vaccination defined as resulting in:
- Death or is life-threatening (immediate risk of death) incident
- Hospitalization or prolongation of existing hospitalization
- Disability: Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- Congenital anomaly / birth defect

Introduction

Most Canadians assume a "robust" surveillance system exists in Canada for monitoring adverse reactions/events following vaccination. This surveillance data is used to reassure politicians, the public and health professionals that vaccines are safe. Further, there is an assumption that this information is readily available to the public to assist them in making an informed decision about vaccinations. We find these assumptions to be incorrect.

The data on vaccine-related injuries is largely unavailable for public scrutiny. Additionally, the data tracking and collection of adverse reactions/events following vaccinations in Canada is seriously flawed in both quality and quantity. The fractured reporting systems do not offer the public any understanding of how many total reported incidents are occurring, nor how these reported incidents relate to the **actual number** of incidents occurring.

The following is an investigative report on Canada's surveillance of and reporting on suspected vaccine-related injuries. It includes discussion of information and data that are critical to making informed medical decisions regarding vaccines, yet remain unavailable to Canadians, though not necessarily to citizens of other countries.

The most significant revelations of this report are the following:

1) **The Canada Vigilance (CV) Database**, overseen by MedEffects™ Canada, despite being billed as publicly accessible, **is not usable in any meaningful way by the public.** The new *Vaccine Safety Reviews* (see right) are too brief to offer meaningful information to the public.
2) **The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) database**, overseen by the Public Health Agency of Canada (PHAC), **is seriously under-reporting adverse events in Canada.** Further, reports on the data select only certain information for release to the public.
3) **Informed consent to vaccination is not achieved due to the current lack of information or quality of information available to Canadians.**

The Canada Vigilance Program Safety Reviews

In late 2015, I became aware of the publication of a new quarterly safety review of the CV database. The minimal data that was released prompted much of this report. Both reviews released so far are reproduced here so the public can see and assess what information is being released to the public regarding the Canada Vigilance Adverse Event database. Note: The introductory paragraph (not included here) are available through the links to each Review.

Text of CV Program 2015 Vaccine Safety Reviews

First Quarter of 2015 Review

From January 1, 2015 to March 31, 2015, the Canada Vigilance Program received **229 reports** of adverse events for which vaccines were the suspected cause.

There were more reports received during this period than was previously received during the same period of 2013 (125 reports) and 2014 (129 reports). This increase was because of the reports involving **Bexsero** (multicomponent meningococcal B vaccine [recombinant, adsorbed], 57 reports) and **Zostavax** (zoster vaccine live, attenuated [Oka/Merck], 51 reports).

There were 94 (41%) serious reports. Most of these involved patients with underlying medical conditions and were unlikely related to the vaccination.

The most frequently reported AEFIs were vaccination site erythema, pain in the extremities, fatigue, vaccination site swelling, headache, pyrexia, vaccination site pain, nausea, vomiting and erythema. The majority of these adverse events involved **Bexsero, Zostavax, and influenza vaccines**. These are known events following immunization and are captured in the respective Canadian product monographs.

No new safety signals (potential safety issues) were identified during this period. **The benefits of vaccines authorized in Canada continue to outweigh the risks.**

Second Quarter of 2015 Review

From April 1, 2015 to June 30, 2015, the Canada Vigilance Program received **171 reports** of adverse events for which vaccines were the suspected cause.

There were more reports received during this period than was previously received during the same period of 2013 (106 reports) and 2014 (149 reports). This increase was because of the reports involving **Bexsero** (multicomponent meningococcal B vaccine [recombinant, adsorbed], 44 reports) and **Zostavax** (zoster vaccine live, attenuated [Oka/Merck], 38 reports).

There were 68 (40%) serious reports. Most of these involved patients with underlying medical conditions and were unlikely related to the vaccination.

The most frequently reported AEFIs were pyrexia, vaccination site pain, vaccination site erythema, pain in the extremities, headache, vaccination site swelling, myalgia, fatigue, nausea, and dizziness. The majority of these adverse events involved **Bexsero, Zostavax, and pneumococcal vaccines**. These are known events following immunization and are captured in the respective Canadian product monographs.

No new safety signals (potential safety issues) were identified during this period. **The benefits of vaccines authorized in Canada continue to outweigh the risks.**

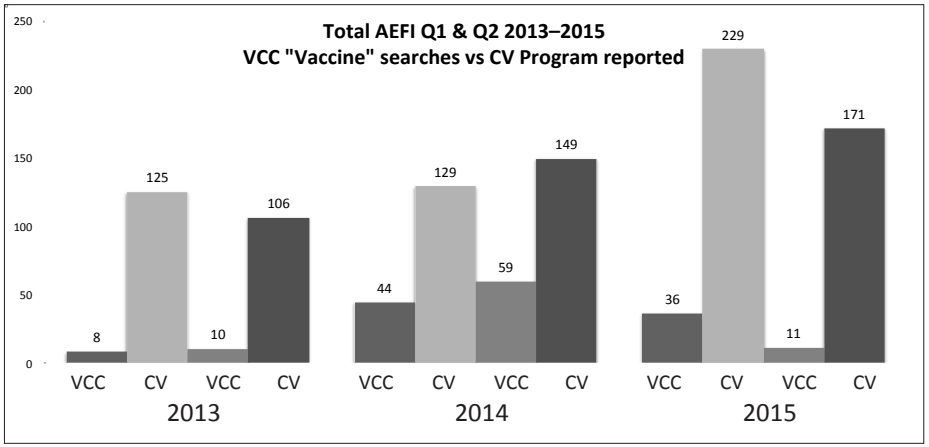
Part 1: The Failure of Canada's Adverse Events Databases

The Canada Vigilance Database

Our examination of the Canada Vigilance database of vaccine-related adverse reactions was originally undertaken on the assumption that the database is a publicly accessible database where vaccine adverse reactions can be searched and analyzed.

That illusion was shattered when a *Vaccine Safety Review* for the first quarter of 2015 was published in the new Health Canada bulletin, *Health Product InfoWatch*. A second quarter 2015 *Vaccine Safety Review* was published at the end of February 2016. In the *Reviews*, the number of vaccine-related adverse reaction reports on the CV database were substantially higher than the number I had found in my previous searches of the CV database.

After much inquiry, I eventually discovered the reason for the discrepancy between my numbers and those reported in the *Vaccine Safety Reviews*. I had been searching the CV database using the words "vaccine(s)" assuming I was pulling up all the data on vaccines. I couldn't have been more wrong. Here is a chart that shows how many reports are generated using my "vaccine" search criteria compared to what the Canada Vigilance Program reported in their Q1 and Q2 *Safety Reviews*.



After a number of emails and phone calls to Health Canada, I finally had the information needed as a member of the public to search the CV database for vaccine adverse events. In a reply letter to my enquiries, the Canada Vigilance National Office of the Marketed Health Products Safety and Effectiveness Information Bureau **makes clear the limitation of the CV database**:

> "**The main limitation for vaccine searches using the online database is that a search for drug class e.g. vaccine, is not available at the present time.** As you encountered, a search using the keyword "vaccine" only retrieves trade names containing the word "vaccine" in the drug name e.g. "Hepatitis B vaccine". Such a search would fail to retrieve trade names that do not contain the word "vaccine" e.g. Zostavax II.
>
> Our **in-house search tool** allows us to search by drug ATC, a drug classification system. Searching by ATC allows us to conduct a complete search of the vaccine class." –Canada Vigilance National Office reply

What it comes down to is this: to capture overall information, each vaccine must be searched separately not only by the trademark name, but also by any other common name entered on any adverse reaction report. You have to guess at these. Even if you are searching for only one type of vaccine to see adverse events for any time period, you need to be conversant with both the trademark name and the common names that might be used on an adverse reaction report.

Let me give you an example so you understand why this renders the database largely useless for statistical analysis. To find the data on all reports for Influenza Vaccines the following searches are required:

1) The 8 trade names—Agriflu®, Fluviral®, Fluzone®, Influvac®, Vaxigrip®, Fluad®, Intanza® and FluMist®
2) The common names—influenza vaccine(s), flu vaccine(s) and influenza virus vaccine(s).
3) Each of the searches also has to be done three times, first to access all reports and then to access serious reports, and then to access any reports of fatalities (or other specifics of interest).
4) In order to compile files on a yearly or quarterly basis, a search also has to be done for each time period of interest.

The result for the five-year period I chose was 30 discrete pdf files for flu vaccines that included 300 Serious Adverse Reaction reports. But this is no longer a database. Each report is an individual page in a large pdf file.

There are 67 separate vaccines on the list of vaccines available in Canada. See the *Canadian Immunization Guide*. In order to collect adverse reaction data on all 67 vaccines for the five years from 2011–2015 would require some **1,500 searches**. This is not how searchable databases are supposed to work. Nor is the product you are left with in any usable form.

The public has no access to properly configured software for searching the

Canada Vigilance database. When the government searches, they search by ATC codes; and they also have a special search function that allows them to search by "suspect" drug products. The cover sheet for their search of all vaccine-related adverse reaction reports in the first quarter of 2015 shows 62 different ATC codes entered to pull up all the vaccine-related reports. There are no functions to search by ACT code or "suspect" vaccine on the search page the public has access to for searching the CV database.

The whole point of computer databases is their flexibility, the ability to sort data by various categories. Without proper search functions a database is no more functional than a filing cabinet full of paper files.

The CV Database was Never Intended to Provide Complete Data To the Public

What is evident is that the CV database was never intended to provide the public with access to comprehensive adverse reaction information. There is no way to search for adverse reactions related to any group of products on the database, whether that be vaccines or a subgroup of vaccines, or pharmaceutical drugs or a subgroup of those drugs. In spite of claims that Canada has a public, accessible adverse reaction reporting system, **the CV system is functionally inaccessible for the public and therefore useless as a tool to assist in determining vaccine safety or making informed health decisions.**

More problems with the CV database data

Duplicate and Erroneous Files

There are many duplicate and erroneous files in public searches, thus the CV database is not useful for comparison to other databases or for statistical purposes.

For example, in the report shown here there are 4 vaccines named. This same report will turn up in DTaP, Influenza, MMR and Varicella searches. Thus the one report would be counted 4 times. Further, in this report, DTaP and Flu vaccine are **not** considered as suspect by the hospital pharmacist who submitted the report. Yet these reports will still appear in a search as a 'serious report' for those 2 vaccines, even though they are not suspect products in the opinion of the reporter.

Partial Adverse Events Data

Only some of Canada's vaccine-related adverse event reports are posted to the CV database. Using the numbers from the first quarter reports for each database, the proportion of data on Canada's two tracking systems looks like this for Q1 (Jan–Mar) 2015.

	Number All reports # (%)	Serious reports # (%)
CAEFISS AEFI	744 (76%)	70 (44%)
CV AR	238 (24%)	90 (56%)
Total	982 (100%)	160 (100%)

So even if a citizen figures out **how** to access data on the CV database, they will be looking at only some of the events. For this time period, it is 24% of all Canadian reports and 56% of all Serious reports.

Discrepancies in the government's own searches

The Q1 CV Safety Review reproduced on page 3, says there were a total of 229 reports for that quarter, yet the government summary sheets sent to

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2016-01-22 - 01:29:52 PM
Initial Received Date: 2015-01-01 to 2015-09-30
Latest Received Date: N/A
Total Number of Reports: 3 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
000646635	0	2015-03-15	2015-03-15	Hospital		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Male		22 Kilograms	Unknown

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)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
DIPHTHERIA AND TETANUS TOXOIDS WITH PERTUSSIS VACCINE ADSORBED (DTaP)	Concomitant	LIQUID INTRAMUSCULAR	Intramuscular			1.0 Day(s)	
INFLUENZA VACCINE (Flu)	Concomitant	NOT SPECIFIED	Intramuscular			1.0 Day(s)	
MEASLES MUMPS RUBELLA VIRUS VACCINE (MMR)	Suspect	LIQUID SUBCUTANEOUS	Intramuscular			1.0 Day(s)	Immunisation
VARICELLA VACCINE (Chicken pox)	Suspect	NOT SPECIFIED	Intramuscular			1.0 Day(s)	Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.18.1	
Decreased appetite	v.18.1	
Febrile convulsion	v.18.1	
Vomiting	v.18.1	

me show a total of 238 reports. The Safety Review also says there were 94 serious reports, yet the government summary sheet for these searches says there were 105 serious reports. So the discrepancies are 9 fewer of all reports and 11 fewer serious reports. I asked about this discrepancy and received the following reply from the National Canada Vigilance Office:

> "Another concern that was raised was that there appeared to be a discrepancy in the total number of reports retrieved for various drug products for the quarterly period using the online database versus the Safety report.
> This discrepancy can be explained by:
> • Ongoing **Quality Assurance activities** in particular with Bexsero reports (which caused modification of the suspect product selection)
> • Reports for this period that were entered at a later date and thus not captured in the vaccine Safety Review report."

I have no idea what is meant by "modification of the suspect product selection" since they are not supposed to be changing data on the records, just entering data into the database. But we can conclude that even the government has problems retrieving accurate report counts from this database.

Incomplete Data

The CV database has an inordinately high number of "unknown ages." For all Q1 2015 reports, it was reported as 24%, and for serious reports it was reported at a whopping 34%. Canada's other database, CAEFFIS, reports only 1.1% of unknown age on all reports and 1.3% on serious reports for the entire year of 2014.

This missing age data speaks to the fact that reports received from manufacturers (the bulk of reports on the CV database) tend to have even less information than the already limited data on the reports submitted from other sources such as those from hospitals, public health nurses, pharmacists, physicians and consumers.

Quality of Data Comparison: CV and VAERS

Now let's compare the quality of data in CV reports to reports from the American VAERS database. To the right is an example of a CV database report on a death related to the Shingles vaccine Zostavax.

All we can gather from this serious CV report is that the patient was a 93 year old man who died, probably in early October or late September of 2014.

Now compare the CV report to a similar Zostavax death report from VAERS, reproduced here and on the following page. **Note particularly that the date of vaccination, date of onset of symptoms and the number of days after vaccination are clearly spelled out on the VAERS report forms.** This information is critical to determine causality of adverse reactions, but is completely absent from the CV report forms. Here is the beginning of this VAERS report:

VAERS ID: 574143 (history) **Vaccinated:** 2014-10-14
Age: 79.0 **Onset:** 0000-00-00
Gender: Male **Submitted:** 2015-01-29
Location: Foreign **Entered:** 2015-01-29

Life Threatening? No
Died? Yes
Date died: 2014-12-14
Permanent Disability? No
Recovered? No
ER or Doctor Visit? Yes
Hospitalized? Yes, ? days

Vaccination	Manufacturer	Lot	Dose	Route	Site
VARZOS: ZOSTER (ZOSTAVAX)	MERCK & CO. INC.			IM	RA

The report continues (on the following page) with more data, including a list of symptoms that are linked to definitions, which pop up on the screen and make understanding the reports much easier.

Canada Vigilance
Summary of Reported Adverse Reactions

Initial Received Date: 2013-01-01 to 2013-12-31
Latest Received Date: N/A
Total Number of Reports: 53 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
000561740	1	2013-10-08	2013-10-24	MAH	1310CAN001367	Study	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
93 Years	Male			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)
AGGRENOX	Concomitant	CAPSULE, EXTENDED RELEASE					
BISOPROLOL	Concomitant	TABLET					
CIPRALEX	Concomitant	TABLET					
GLICLAZIDE -TAB 80MG	Concomitant	TABLET					
LASIX	Concomitant	NOT SPECIFIED					
THYROXINE	Concomitant	NOT SPECIFIED					
ZOSTAVAX II 0.65ML SINGLE-DOSE VIAL, REFRIGERATOR STABLE.	Suspect	POWDER FOR SUSPENSION SUBCUTANEOUS	Unknown	0.65 mL			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version
Unresponsive to stimuli	v.18.1

Symptoms: Acute hepatic failure, Blister, Blood bilirubin increased, Confusional state, Death, General physical health deterioration, Herpes zoster, Immunoglobulin therapy, Influenza like illness, Injection site rash, Intensive care, Lethargy, Malaise, Mechanical ventilation, Multi-organ failure, Pyrexia, Rash, Rash vesicular, Respiratory failure, Varicella virus test positive, Varicella zoster virus infection, Viral test positive

SMQs:, Liver related investigations, signs and symptoms (narrow), Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (narrow), Severe cutaneous adverse reactions (broad), Anaphylactic reaction (narrow), Acute pancreatitis (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (broad), Torsade de pointes, shock-associated conditions (broad), Hypovolaemic shock conditions (broad), Toxic-septic shock conditions (broad), Anaphylactic/anaphylactoid shock conditions (broad), Hypoglycaemic and neurogenic shock conditions (broad), Dementia (broad), Acute central respiratory depression (narrow), Biliary system related investigations, signs and symptoms (narrow), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Hypersensitivity (narrow), Tumour lysis syndrome (broad), Respiratory failure (narrow)

Other Medications: No other medications

Current Illness: Unknown

Preexisting Conditions: Lymphoma; 04/2014, rituximab, Chronic lymphocytic leukaemia; 04/2014, fludarabine phosphate, Chronic lymphocytic leukaemia; 04/2014, cyclophosphamide, Chronic lymphocytic leukaemia

Diagnostic Lab Data: Blood bilirubin, very high, increased; Bronchoalveolar lavage, initially positive for varicella zoster virus; Bronchoalveolar lavage, became negative for varicella zoster virus; Laboratory test, vesicle fluid confirmed clinical imp. of v. zoster; Viral test, positive for shingles vaccine

CDC Split Type: WAES1501**GBR**010409

The report then ends with a full discussion of what took place in this case:

"**Write-up:** Information has been received from Sanofi Pasteur MSD (SPM) (manufacturer control #E2015-00473) on 26-JAN-2015. Initial case received on 21-Jan-2015 from health authority. GB-MHRA ADR 22824299. The case is medically confirmed as it was reported by a physician. A 79 year old male patient, with medical history of lymphoma, received an injection of ZOSTAVAX (batch number K00514, invalid) intramuscularly in the right deltoid, dose in series not reported, on 14-Oct-2014. On an unreported date, 2 weeks after the vaccine, the patient experienced flu like symptoms and lethargy and was unwell. On 19-Nov-2014, the patient was admitted to hospital with rash, consistent clinically with varicella zoster virus infection, was febrile and slightly confused but had no respiratory symptoms. Rash initially developed around the injection site on right deltoid but then developed widespread vesicles. On admission, the patient was treated with high dose of intravenous aciclovir. **Subsequent vesicle fluid analysis confirmed the clinical impression of varicella zoster virus.** He continued to develop new skin lesions over the next few days but remained clinically stable. On 24-Nov-2014, the patient rapidly deteriorated with respiratory failure requiring transfer to intensive care and invasive ventilation. With the increased doses of intravenous aciclovir and intravenous immunoglobulin the patient received, his skin became clear and subsequent bronchoalveolar lavage which had initially been positive for varicella zoster virus became negative. Despite this, the patient continued to deteriorate. He was extubated and briefly improved. For a short duration he was able to communicate with his family before deteriorating again. On an unreported date, the patient developed acute liver failure with a very high bilirubin which was already unexplained. On 14-Dec-2014 the patient died from multi-organ failure. The patient was treated with cyclophosphamide, fludarabine and rituximab chemotherapy until Apr-2014 for chronic lymphocytic leukemia that was why the patient was known in haematology department. **The reporter had confirmation from colleagues in virology that the strain of varicella zoster virus identified was that of the shingles vaccine** and therefore the case was reported to agency. At the time of reporting, the patient had recovered from varicella-like rash and varicella zoster and he had not recovered from acute liver failure, confusion, fever, flu like symptoms, lethargy, respiratory failure and unwell. On 14-Dec-2014, the outcome of multi-organ failure was fatal. The case was considered as serious due to the patient''s death and hospitalisation.

Source: http://www.medalerts.org/vaersdb/findfield.php?IDNUMBER=574143"

It is blatantly obvious that if a member of the public wanted information about vaccine-related adverse events, the information provided in the CV database is grossly inadequate for making informed decisions. They would be much better off using the VAERS database to understand the risk of adverse reactions to specific vaccines.

The VAERS database also has an easy to use search engine that was developed by the non-profit National Vaccine Information Centre (NVIC) for ease of public searches. This search engine offers a multitude of search functions and report formats including graphs. The default setting prints a summary report for every search with an age breakdown. Here are the summary tables for 1) All vaccine-related Serious reports on the database to date and 2) Serious reports on Influenza vaccines for 2011–2015:

Found 68,807 cases where Serious

Table

Age	Count	Percent
< 3 Years	27269	39.63%
3-6 Years	3400	4.94%
6-9 Years	1141	1.66%
9-12 Years	1402	2.04%
12-17 Years	4745	6.9%
17-44 Years	12321	17.91%
44-65 Years	7570	11%
65-75 Years	3445	5.01%
75+ Years	2798	4.07%
Unknown	4716	6.85%
TOTAL	68807	100%

Found 4097 cases where Influenza vaccines: Serious from 2011–2015

Table

Age	Count	Percent
< 3 Years	465	11.35%
3-6 Years	206	5.03%
6-9 Years	77	1.88%
9-12 Years	88	2.15%
12-17 Years	116	2.83%
17-44 Years	844	20.6%
44-65 Years	1066	26.02%
65-75 Years	645	15.74%
75+ Years	479	11.69%
TOTAL	4097	100%

VAERS and its search engine could well serve as a model for the overhaul of the Canadian Adverse Events tracking systems. See also the brief discussion at the end of this section on the Swiss Adverse Events system and their public reports.

Conclusion:
The ease of use and quality of information on the VAERS database should give Canadian citizens and their government health agencies a better understanding of what kind of information a truly informative adverse reactions database should be collecting and also how a truly functional public search engine works to make that information accessible.

Vaccine Information: What We Don't Know

The lack of transparent adverse event information is compounded by the lack of public information in Canada about vaccines themselves and about our vaccine programs. It is difficult to impossible to make sense of adverse events data without the following information also being readily available to Canadians.

How Much?

Costs related to vaccines are not readily available. We do not know how much Health Canada spends on vaccines on an annual basis. We do not even have access to government contract cost for individual vaccines. This information should be easily available since our tax dollars are spent to purchase these products. Nor can we readily find how much the federal and provincial or territorial governments spend on the gigantic bureaucracies that oversee and manage the vaccination programs in Canada.

Nor do we know how much vaccine-related injuries cost our public health care systems. We have reason to believe the cost is significant. But if it is tracked, it is not divulged to the public. As explained in the Zostavax section of this report, not all governments include adverse events in cost benefit analysis of vaccination programs. Yet they don't hesitate to include benefits like estimated days of work saved or health care costs saved due to vaccination. **As citizens we cannot arrive at any conclusions on the cost benefits analysis of the vaccination programs without full information.**

How Many?

Further, we do not know how many vaccines are distributed in total or by individual vaccine type. And of those distributed, we do not know how many are actually administered or returned/disposed of. This is all apparently privileged information of the manufacturer.

Though general distribution numbers are known to PHAC, as evidenced by some rate calculations in their CAEFISS reports, great care is taken that no distribution numbers for individual vaccine products is divulged to the public. **The lack of information on distributed or administered vaccines makes it impossible for anyone to determine and compare the rates of adverse events for various vaccines.**

Who?

About the only the facts we do have on who is receiving vaccines can be inferred from some population data and a bit of national vaccine coverage data on children. For example, the birth rate in Canada is about 400,000 babies per year. In the first year life for these babies approximately 11 vaccines will be administered to most of them. So we can infer that over 4 million vaccines are administered annually to babies ≤1 year old.

As to other segments of the population, according to the July 2015 StatCan report, the elderly population (≥ 65 years old) is 16% of the population. And children ≤14 years old comprise another 16% of the population. So that means those between the ages of 15 and 64 comprise 68% of the population. **The most vaccine-targeted portion of the population is the 32% made up of 16% elderly and 16% children.** The total population in the 2015 report is 35.9 million, so children 14 years of age and under and the elderly account for 11.5 million people. We can only imagine how many million doses of vaccines are administered to this target audience. Why is this information not readily available?

As to recent vaccine coverage, we only know the national vaccine coverage estimates for babies up to 2 years old for 2013, but not for any other age group. We are still waiting for the PHAC 2013 national coverage report on all school age children (day care, preschool, elementary and high school) that was to be released in late 2015. (See our July 2015 Update Report for details.)

Rare Adverse Events or Rare Reporting?

One more important topic that needs to be considered is the question of the number of reported vaccine-related adverse events. We have all heard that serious adverse events are rare. "One in a million" is a favorite media mantra. This is a very deceptive statement.

This "one in a million" is likely based on the number of serious vaccine related injuries that were **compensated** during an 8-year period by the USA Vaccine Injury Court (pdf). In the court reports, under the page 1 heading *How many claims have been compensated?* one reads the following information:

"From 2006 to 2014, over 2.5 billion doses of covered vaccines were distributed in the U.S. according to the CDC. 3,300 claims were adjudicated by the Court for claims filed in this time period and of those 2,054 were compensated. **This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.**"

To put those **2,054 compensated cases** in context, the VAERS database has **33,445 serious adverse event reports** during that same 8-year time period.

Conclusion: The "1 in a million" compensation rate for serious events has nothing to do with the rate of serious adverse events reported for any specific vaccine or for all vaccines. Further, doses distributed is not the correct denominator in any calculation of reporting rates of adverse events. Doses administered should be the number used to arrive at reported adverse event rates.

Reporting Rates: Actual Events vs. Reported Events

There is one further concern in how the public is informed of the "rate of adverse events". **The fact is no one knows how many actual adverse events occur.** Even in the USA where health professionals are required by law to report all adverse events, the estimates of how many events are reported varies from **1% to 10% of actual events occurring**. In Canada, it is generally claimed by government health agencies that we have a 10% reporting rate, although I have been unable to find any specific evidence to support this claim.

I have found only one small clue as to the number of **actual** vaccine-related adverse events occurring in Canada. The last annual CAEFISS Report (Dec 2014) gave a reporting rate based on vaccine doses distributed:

"A total of 46,481,347 doses of vaccine were distributed in Canada in 2011 and 2012, giving reporting rates per 100,000 doses distributed of 15.2 for all AEFI and 0.85 for SAE."

I remind you we have no idea how many vaccinations were actually administered of those distributed doses, so even this calculated rate is low. But using these figures (since they are all we have), if they represent only 10% of AEFIs that are actually occurring, then the **actual occurrence** becomes 152 AEFIs per 100,000 doses, and 8.5 SAEs per 100,000 doses. If they represent only 1% of adverse events that are actually occurring, then the rate is 1,520 AEFIs per 100,000 doses, and 85 SAEs per 100,000 doses. This point is never made clear in government reports. **They present the figures as though these were the rates of ACTUAL adverse events, not the rates of REPORTED adverse events.** The much lower reporting rate of 1% is quite likely what is happening in Canada as you will see when we analyze CAEFISS reporting rates in the following pages. Here is the data presented in table format for easy reference:

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

Remember these are average rates for **all vaccines** given to the **entire population**. According to this average reporting rate, only 5.6% of reported adverse events are serious. The percent of serious reported reactions/events is much higher on both CV and CAEFISS databases ranging from 40–60% due to the sources of the serious reports (manufacturers and pediatric hospitals respectively). **Both CAEFISS and CV report an increase in the percent of serious events over the last few years.**

Data on suspected vaccine-related deaths is restricted

The CV database is the only place the public has access to numbers of suspect vaccine-related deaths. Although there is a search function for a fatal outcomes, as we have seen finding the group of vaccine reports on which to use this function is a very laborious process and unlikely to be utilized by the public.

CAEFISS reports occasionally mention fatalities in special reports on vaccines of concern, but deaths are not routinely noted in the information they make public.

In contrast, VAERS currently shows 6,105 deaths over the life of the database. More than half (55%) of these suspected vaccine-related deaths are for toddlers or babies less than 3 years old.

Found 6105 cases where Patient Died

Table

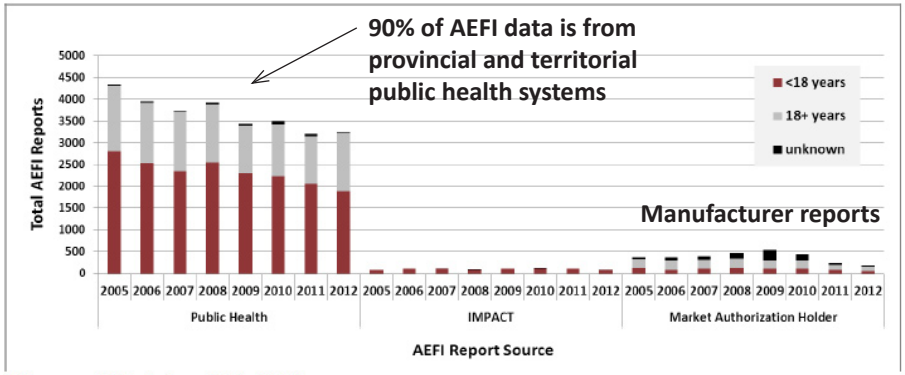
Age	Count	Percent
< 3 Years	**3372**	**55.23%**
3-6 Years	**137**	**2.24%**
6-9 Years	**61**	**1%**
9-12 Years	**61**	**1%**
12-17 Years	**154**	**2.52%**
17-44 Years	**362**	**5.93%**
44-65 Years	**375**	**6.14%**
65-75 Years	**329**	**5.39%**
75+ Years	**564**	**9.24%**
Unknown	**690**	**11.3%**
TOTAL	**6105**	**100%**

Part 2: CAEFISS Database

Now let's look at Canada's second database, CAEFISS—the Canadian Adverse Events Following Immunization Surveillance System. It differs from the CV Database in a number of ways in addition to the one discussed on the previous page regarding Adverse Reactions versus Adverse Events.

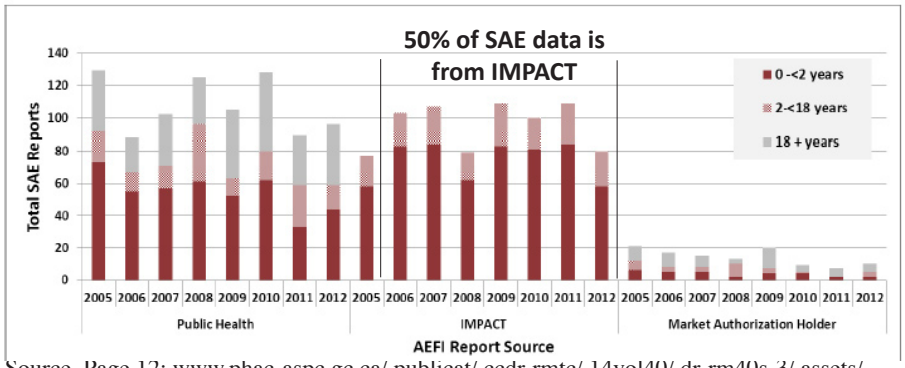
First, it contains only adverse events reports following vaccines unlike the CV database that includes reports on all drug products. Second, it is not publicly accessible on-line. The public must depend on published reports of selected data. Third, CAEFISS is a combination active and passive reporting system. The IMPACT program in pediatric hospitals is promoted as the active part of the reporting system. Since the children these reports relate to are in hospital, this means all the IMPACT reports are serious adverse event reports (SAEs). Thus IMPACT reports comprise a very small portion of all AEFI reports on the database, but about half of the SAE reports. The bulk of the data (up to 90%) is from the passive provincial and territorial (P/T) reporting systems and includes data on all ages, not just children, and all reports, not just serious ones.

Figure 1A: AEFI[1] reporting sources for children and adults by year vaccine administered, 2005–2012



[1] Adverse event following immunization (AEFI)

Figure 1B: Serious AEFI[1] (SAE)[2] reporting sources for children and adults by year vaccine administered, 2005–2012



Source, Page 12: www.phac-aspc.gc.ca/ publicat/ ccdr-rmtc/ 14vol40/ dr-rm40s-3/ assets/

Since the policy change in 2011 manufacturers (MAH) are supposed to report to the CV Database, not CAEFISS. However, some were still reporting to CAEFISS in 2012 according to Figure 1A &1B from the last national surveillance report published in 2014. Unfortunately the information on percent of reports from the 3 reporting sources (IMPACT, P/T Public Health, MAH) is no longer available in the CAEFISS Quarterly Reports.

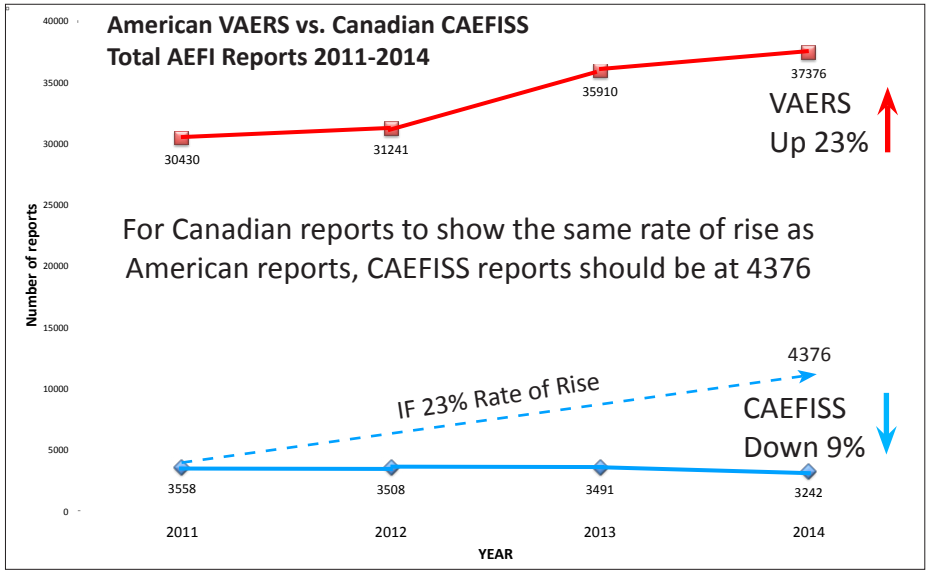
The CAEFISS Quarterly Reports are now being published on the "Healthy Canadians" site rather than the PHAC web site. The reports themselves have changed format and are a bit dumbed down. The first quarter report for 2015 (Jan–March) is found here and the second quarter report (April–June) here.

Since the 2014 second quarter report 2 years ago the CAEFISS quarterly reports have noted:

> "As in previous quarters the total count of AEFI reports received was lower than that seen in previous quarters reflecting a gap in reporting from jurisdictions that are implementing new electronic reporting systems."

Why Are CAEFISS Reporting Rates Declining?

Despite a growing population and more vaccines licensed every year in Canada, the number of all reports continues to decline. This prompted me to



investigate the reporting rates on CAEFISS for the full years 2011 through 2014 and compare that to the reporting rates on the American VAERS database during the same period of time. Since Canada has almost the same number of licensed vaccines and similar child immunization schedules, we should see similar reporting rates to those in the USA. This, however, is not the case.

As the chart on the previous page shows, while VAERS reporting rates have increased by 23% over the 4-year period, CAEFISS rates have declined by 9%. This 9% decline can be partly explained by the policy change in 2011 since MAH reports were approximately 10% of all reports on CAEFISS. However, this still does not explain why the number of CAEFISS reports has remained essentially static since 2011 instead of increasing with growing population and growing numbers of vaccines coming onto the market in Canada.

Even worse, the chart to the right shows that CAEFISS reports have actually been on the decline since 2005. So the switch to electronic reporting systems cannot account for the decline over 10 years, especially since the decline for that reason was only noted in April of 2014 in the quarterly reports.

If VAERS is reporting 1%–10% of actual adverse events and shows steady increase in numbers of reports, this means actual events are increasing. What possible percent of actual adverse events can CAEFISS be reporting given it shows a steady decline? Surely not 10% as PHAC and Health Canada claim. The percent of actual adverse events that are being reported must be much lower than 10% and it continues to decline.

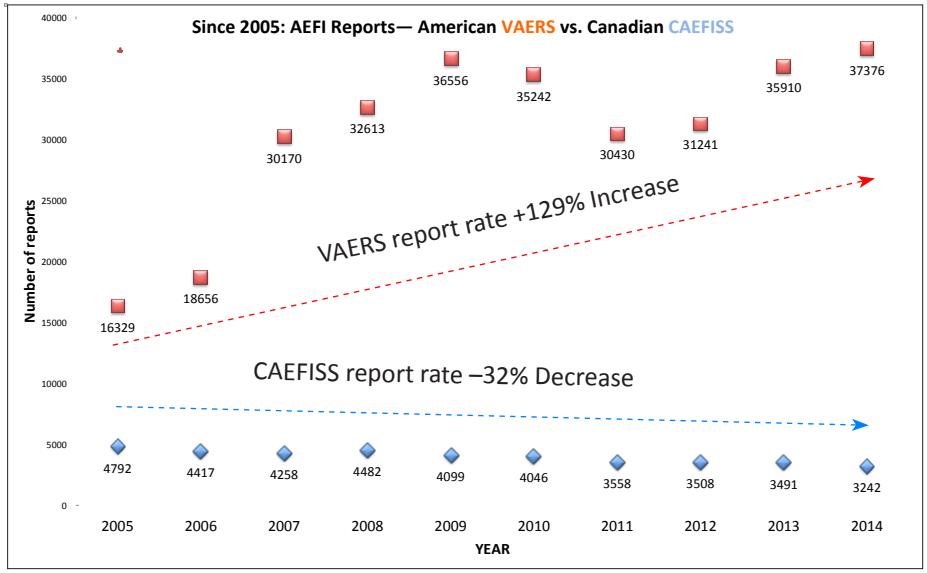
A detailed discussion of the adverse event reports for Q1 and Q2 2015 for CAEFISS appear in Part 2 of this report. First let's turn to a discussion of disease incidence, vaccine coverage and safety reporting with some European comparisons.

How Two European Countries Report Vaccine Information

United Kingdom

When I searched the internet for "vaccine coverage for England" the first page that popped up was from the government of UK Collection, Health Protection Reports and what a beautiful page it is. The subheading is *Routine data and commentary reporting on infectious diseases*.

Immunization is the first category there, followed by a list of **both vaccine coverage and disease incidence reports**. Obviously the English understand the link between disease incidence and vaccine uptake. They make this data easily accessible to the public in one location, and **the quality of data is suburb**.



Vaccine Coverage in the UK

Since we are in the tail-end of flu season, I opened Seasonal flu vaccine uptake in GP patients: 1 September 2015 to 31 January 2016 (pdf). The data is current and its quality excellent. This is because doctors actually report the data to public health authorities. The first chart in the report is a reporting response summary that shows 7,679 GP practices in England with 98.8% of them reporting with vaccine uptake data.

The summary is followed by 10 tables broken down by age and risk, including pregnant women and the youngest children. The **ACTUAL NUMBER of VACCINATED** in each group is recorded. Reproduced below are two of the 10 tables in the report. The first is for the elderly and the second is for all other ages who are considered at risk of complications from influenza infection.

65 years and over					
2015/16			2014/15		
Patients registered	Number vaccinated	% Vaccine Uptake	Patients registered	Number vaccinated	% Vaccine Uptake
9,921,156	7,040,630	71.0	9,836,086	7,154,857	72.7

6 months to under 65 years at-risk [2,3]					
2015/16			2014/15		
Patients registered	Number vaccinated	% Vaccine Uptake	Patients registered	Number vaccinated	% Vaccine Uptake
6,787,958	3,063,355	45.1	6,033,608	3,033,392	50.3

This is in striking contrast to how Canada collects and reports national vaccine coverage data. Every two years, coverage data is collected by phone surveys of small, sample populations. Thus the national vaccine coverage data have been **estimates only**, since those who administer vaccinations in Canada are not required to collect and report **actual data**. For some reason, it also takes at least two years for the information to be released, so it is never up-to-date.

As of March 2016, the 2013 Canadian vaccine coverage estimates have not been fully released. Further the survey did not include the general population, but focused only on child coverage, concurrent with the push in Canada to require full vaccination for school entry. We prepared this chart comparing 2011 released estimates for 2 year old coverage with the 2013 estimates that were released in 2015. It is obvious that coverage rates are declining in this age group.

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

	Disease	2011	2013	Difference
Combination DTaP vaccines	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%
MMR vaccine	Measles	95.2%	89.6%	-5.6%
	Mumps	95.2%	89.2%	-5%
	Rubella	95.2%	89.2%	-6%
	Varicella	88.6%	73.1%	-15.5%
	Meningococcal C	80.5%	88.6%	+8%
	Pneumococcal	76.5%	79.3 %	+3.2%

Conclusion: This is yet another example of how fragmented and non-transparent the Canadian approach is to vaccine-related information.

In the case of vaccine coverage, there is no consistent routine policy to collect and report national coverage data nor an policy to report vaccines administered data. Rather the policy seems driven by fluctuating and unstated agendas.

Disease Incidence in the UK

Returning to the **routine** UK reports, I opened the first report on the list, meningococcal disease incidence. When I clicked on this I was taken to a page with all the quarterly and annual reports on **laboratory confirmed cases of all strains of meningococcal disease.** Below is Table 1 from the Q4 2015 report that contains annual data on **laboratory tested** disease incidence **by capsular group**. The report also had a table based on age distribution of the disease by capsular group.

In the table below, it is obvious that Meningococcal B is the most common strain circulating. Vaccines target different strains of invasive meningococcal disease (IMD). **So disease incidence by strain is very important information for any citizen considering taking one of the many meningococcal vaccines available.**

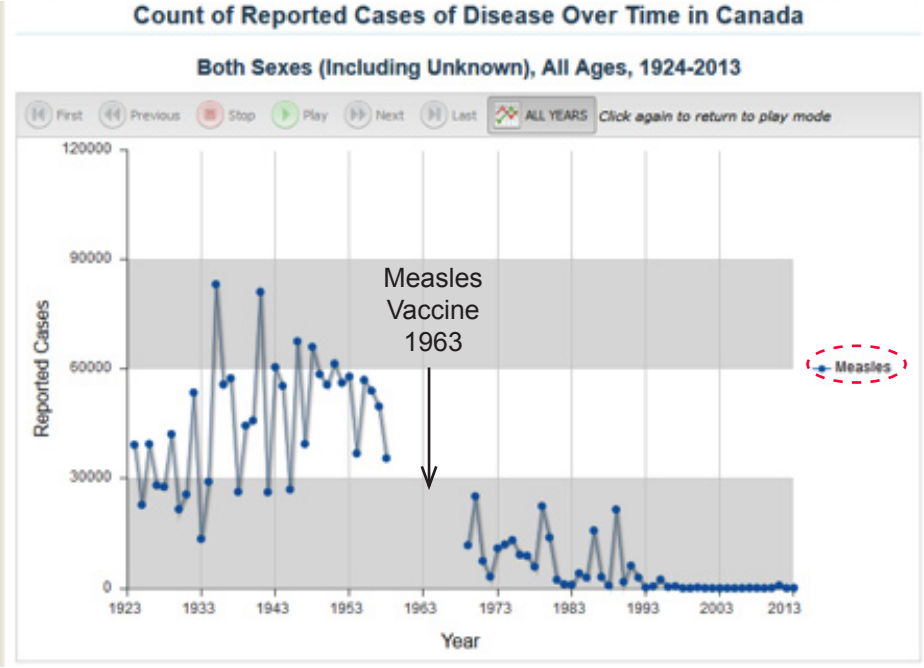
Yet Canada's disease incidence charts do not break out IMD incidence by strain. If a citizen searches on-line they may find one older report that shows testing by strain. But even though there is surveillance of IMD by strain, there is no routine reporting made public except as described below.

National surveillance data of the incidence of reportable diseases is available to the Canadian public at the Notifiable Diseases On-line. There are few different ways of extracting data, which are explained on the index page linked above.

Since much of the recent push for increasing vaccine coverage of school children is based on the measles outbreaks in the US and Canada in the winter of 2015, it seemed appropriate to investigate measles incidence in Canada. The graphic on the next page was generated by the by year, moving line chart when measles was selected from the list of diseases.

Table 1: Invasive meningococcal disease in England by capsular group and laboratory testing method: October - December (Q4), 2015

Capsular groups~	CULTURE AND PCR		CULTURE ONLY		PCR ONLY		Total		Cumulative Total#	
	2014	2015	2014	2015	2014	2015	2014	2015	2014/15	2015/16
	Q4	Q4	Q4	Q4	Q4	Q4	Q4	Q4	Q3-Q4	Q3-Q4
A	–	–	–	–	–	–	–	–	–	–
B	30	31	25	24	52	79	107	134	166	197
C	1	4	6	3	4	3	11	10	15	16
W	7	10	23	43	11	9	41	62	64	88
Y	2	7	12	15	2	3	16	25	24	38
Ungrouped*	–	–	–	–	2	–	2	–	2	3
Ungroupable*	–	–	–	4	–	–	1	4	1	5
Total	40	52	67	89	71	94	178	235	272	347



Noteworthy is that measles, **the supposed scourge that was killing and maiming thousands was not even a reportable disease in Canada for 10 years (**from 1959 to 1969, hence the break in the data). **While oddly, a vaccine was developed and introduced in those very same years.** It is also apparent that disease incidence was cyclical and declining prior to the introduction of the vaccine.

The actual tabulated numbers of reported cases are found below the chart. The number of cases for 2010–2013 are as follows:

2010: 98 2011: **752** 2012: 9 2013: 82

The database has not been updated since 2013. But annual national case numbers for measles can be retrieved from the Measles Surveillance site by reading the last weekly report in each year. For 2014–2015 the number of cases were reported as follows:

2014: 127 2015: **196**

This begs the questions:

- Why the **2011 outbreak of 752 cases** did not generate the media hysteria that the **2015 outbreak of 196 cases** did.
- Whether it is **declining coverage rates** rather than **actual disease incidence** that is driving the current vaccination campaigns.

Conclusion: Canada needs a more complete and accessible reporting system for the incidence of diseases related to vaccines.

Swiss Adverse Event Reports

As a final exercise, we will look at how the Swiss report AEFIs and compare Swiss data to some Canadian data. The latest 2014 "vaccinovigilance" report is available at SwissMedic. It seems the Swiss have the same problem as Canada in terms of missing dosage data, although they don't try to pretend that doses **distributed** is a valid substitute for doses **administered**. Their report begins [Emphasis ours]:

> "During 2014, SwissMedic received 296 case reports of suspected adverse events following immunization (AEFI) from Switzerland. This is a much higher number of reported cases as compared to 2013 (138 reports), which might reflect **an increased incidence of adverse reactions following vaccinations or an increased reporting rate of AEFIs. However, since there are no accurate data available regarding the total number of vaccines/ doses administered during 2014, a straightforward conclusion cannot be drawn.**"

The Ontario count of AEFI in 2014 was reported as follows [Emphasis ours]:

> "Of the 8.4 million **doses distributed** across the province, 568 adverse reactions were reported. And of that number, 23 (or three out of every million **doses distributed**) were considered serious, such as seizures or severe allergic reactions requiring hospitalization."

This Canadian example shows a very different approach to statistical reportage than that taken by the Swiss.

In 2014, Switzerland had a population of 8.2 million. Ontario had a population of 13.7 million. So Switzerland has 60% the population of Ontario. 296 Swiss AEFIs compared to 568 Ontario AEFIs means the Swiss had about 52% the number of reports as Ontario, which is population-size appropriate.

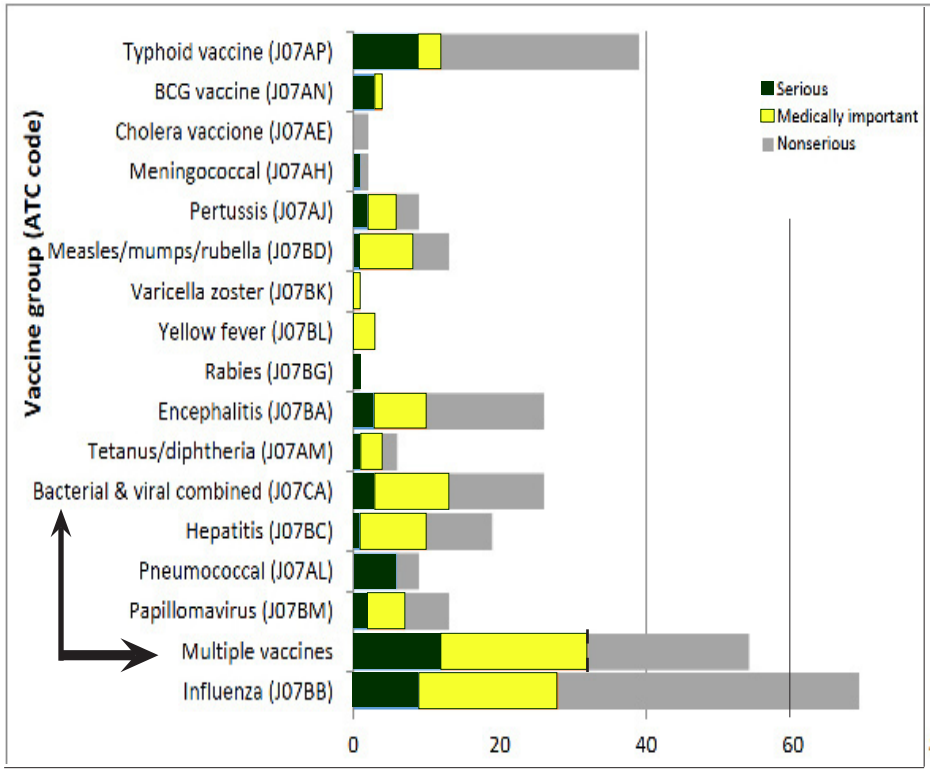
There are a number of other significant differences between Canadian and Swiss reports. In Figure 2 (next page), note the Swiss report both "**multiple vaccines" and "bacterial and viral vaccines" combined.** The often expressed concern of combining vaccinations is not just brushed aside. The Swiss are monitoring this for sound scientific reasons. **Note that multiple vaccines have the most number of serious and medically important events of any other vaccine group in the figure.**

The differentiation between SAEs and Medically Important Events is particularly important since medically important events can be **safety signals** and require changes to product monographs. Remember the definition of safety signals included "unexpected" adverse reactions. Expected adverse reactions are those **listed** in manufacturer literature. **Medically important events are**

(hence unexpected) post-market events that require medical intervention so they do not result in serious outcomes (i.e., death, hospitalization, disability or congenital defects).

In Canada medically important events are considered as serious and not differentiated from other serious events in public reports. (You can see "other medically important conditions" listed with serious events at the top right in CV reports reproduce in this report.)

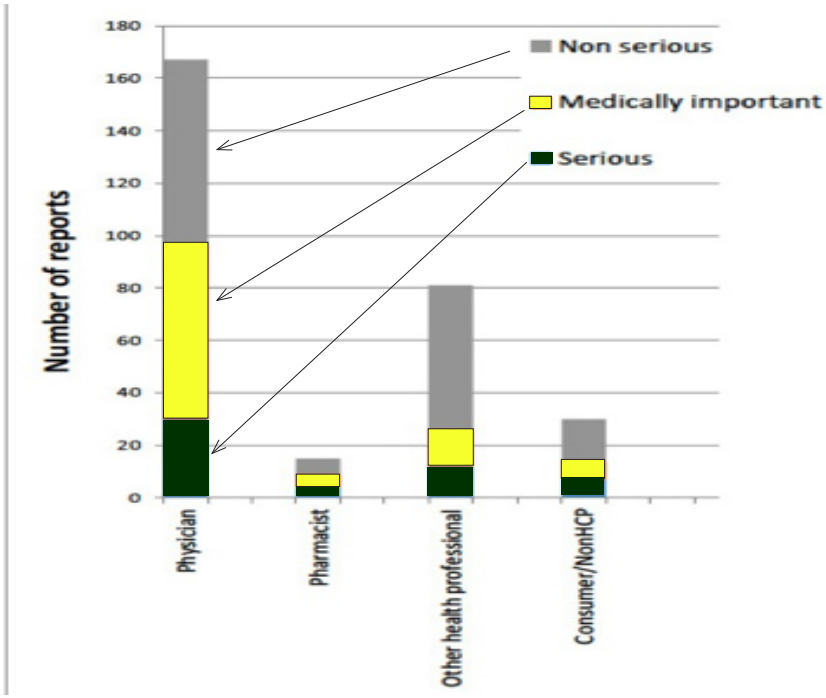
Figure 2. Number of reports per vaccine group (ATC code) and seriousness, 2014



Another difference is that **the proportion of reported Serious Adverse Events to non-serious adverse events is much higher in Switzerland than in Ontario**. The text accompanying Figure 2 explains that of the 296 spontaneous reports received in 2014, 31% were not serious. 51% were medically important and 18% were events with serious consequences. **This means 69% of all Swiss AEFI reports were what we term serious (SAEs). This represents a distinct difference from the Ontario reports where 96% were non-serious and only 4% were serious (SAEs).** Perhaps this is because doctors are encouraged to submit reports in Switzerland and hence they do submit the bulk of all AEFI reports.

Figure 3, shows the source of reports. Manufacturers do not submit reports here, only health professionals and consumers/non-health professionals do. According to the Swiss report, **56% of all AEFI reports are from physicians and 58% of those physician reports were either serious or medically important.**

Figure 3. Number of AEFI reports per reporter qualification and seriousness, 2014



The 10-page Swiss report also includes a table of the number of reports per age group and seriousness, an SOC classification of reports, a figure that lists report numbers by vaccine group and top 3 SOCs involved, and text and tables that name and discuss non-serious and serious events and fatalities. There were 3 fatalities in 2014, and 2 cases of encephalitis, 3 cases of GBS, 2 narcolepsy, 3 MS, and one hypotonic-hyporesponsive episode.

Conclusions:

The Swiss report is a far more informative, clear and transparent adverse event report than what we see in Canada from our various public health agencies. Their method also represents a more responsible and scientific approach to adverse event tracking.

Finally, compared to Canadian doctors, Swiss doctors contribute more significantly to AEFI reporting.

Part 2: Analyzing Data, Investigating Vaccines

Canada Vigilance Data 2011-2015

Although the 2011 through September 2015 CV database searches did not produce statistically usable results due to flaws in the search function, this does not mean that useful data and information cannot be gleaned from the reports. Even though the searches will have missed some reports and duplicated or erroneously noted others as serious, we can still draw certain conclusions.

Fatalities

The 1388 serious reports that turned up in my vaccine search are sorted by vaccine type, as seen in the chart below. There are a total of 13 reports that list death as the outcome in the 4.75 years of reports. That averages to 2.7 deaths per year. **At a 10% reporting rate that would mean an average of 27 actual suspected vaccine-related deaths occurred per year. At a 1% reporting rate it would mean an average of 270 actual suspected vaccine-related deaths per year.** HPV vaccine has the largest number of deaths at four.

Vaccines with highest report rates

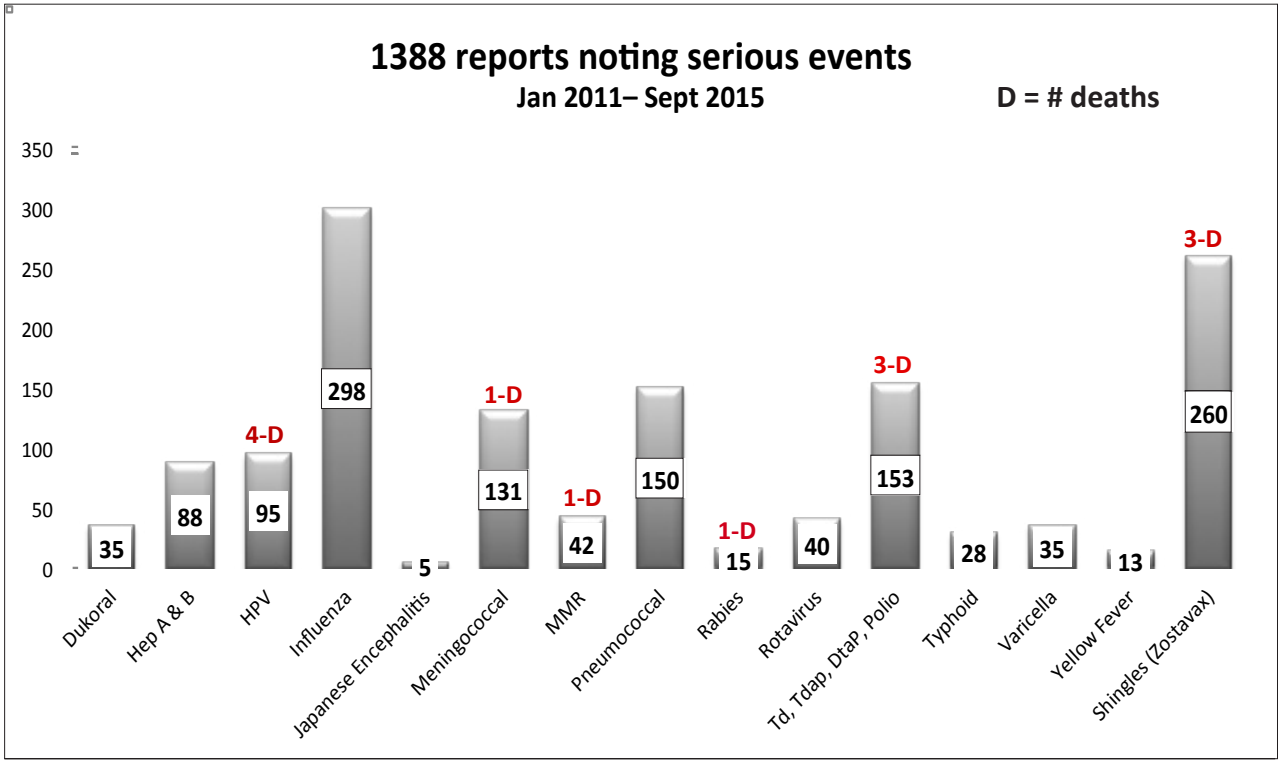
The influenza vaccines have the highest number of serious reports at 298, followed closely by the shingles vaccine, Zostavax, at 260. The next highest categories are the Pertussis combination vaccines at 153, followed by Pneumococcal at 150 and Meningococcal at 131 reports. These are followed by HPV vaccines at 95 and then Hep A & B vaccines (singly or in combination) at 88. MMR at 42, Rotavirus at 40 and Varicella at 35 show the lowest frequencies of the pediatric vaccines. Last are the "travellers' vaccines: Dukoral (cholera) at 35, Japanese encephalitis at 5, typhoid at 28 and yellow fever at 13. Rabies has 15 reports. Even though these reports contain duplicates these trends of serious reports are similar to those seen in the CAEFISS quarterly reports (except for Zostavax).

The number of reports is only one factor in considering adverse events. **What is needed to truly evaluate specific vaccine risk is the number of adverse events reported per doses of the vaccine administered. As we do not know the number of vaccinations administered, it is impossible to determine the actual risk of a specific vaccine when attempting to make informed decisions.**

The target audiences, cost and the severity of the serious events also need to be considered. As to target audiences, the influenza vaccine has the broadest target audience...everyone! Furthermore, since no safety testing is ever done on influenza vaccines. For both reasons, the high number of serious reports is not unexpected. It is also apparent in the CAEFISS data and even in the Swiss data.

In contrast to the influenza vaccine, the shingles vaccine targets about 35% of the population (those 50 and over), is relatively new, and is not publicly funded in most provinces. Yet it has a very high rate of serious reports. This speaks directly to the safety and efficacy of this vaccine as discussed later.

The pertussis combination vaccines (DTaP), MMR, Rota, Varicella, pneumenococcal and meningococcal vaccines target children and babies (with in most cases multiple doses of multiple antigens). Although other age groups can also receive these vaccines for various reasons. Pneumococcal and meningococcal vaccines also specifically target the elderly population (≥ 65).



Canada Vigilance Data Q1 & Q2 2015

In response to my enquiries, the government sent electronic files of their searches of the CV database for Q1 2015. Here is a graphic from the summary sheet from their search of All adverse reaction (AR) reports for the first 3 months of 2015.

They show 238 total adverse reaction reports. **105 or 44% were serious with 2 deaths, 1 life-threatening incident, 16 hospitalizations, 13 disabilities and 84 medically important conditions.**

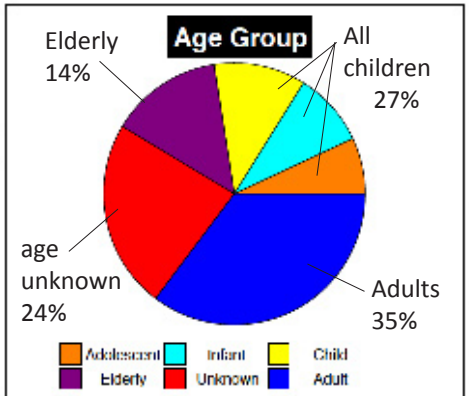
According to the Q1 and Q2 Vaccine Safety Reviews (see page 3), in the first 6 months of 2015 there were a total of 400 AR reports, of which 162 or 40% were Serious. Bexsero (meningococcal B vaccine), Zostavax (shingles vaccine) and pneumococcal (pneumonia) vaccines are mentioned as contributing to the increased number of reports.

Total No. of Reports: 238

Number of reports (percentage) with one or more reaction terms in the SOC(s) above

MedDRA V18.1

Age Group		
Infant	22	9.2 %
Child	27	11.3 %
Adolescent	16	6.7 %
Adult	84	35.3 %
Elderly	33	13.9 %
Unknown	56	23.5 %



Reason for Seriousness	
Death	2
LifeThreatening	1
Hospitalization Required	16
Disability	13
Congenital Anomaly	0
Other Medically Imp Condition	84

Patient Sex		
Female	124	52.1 %
Male	75	31.5 %
Not specified	31	13.0 %
Unknown	8	3.4 %

Serious Reports	
Yes	105
No	133

CAEFISS Data Q1 & Q2 2015

For the first half of 2015 there were a total of 1240 Adverse Event (AE) Reports on CAEFISS. This represents about 70% of the average number of reports for the first half of the previous 4 years. So **the total number of reports continues to decline.**

Looking at Serious Reports only, in the first half of 2015 there were 117 SAEs compared to an average of 109 in the first half of the last 4 years. This is a 7% increase. **As a proportion of All Reports, Serious Reports increased from 8.7% to 9.5%.**

In accordance with the discussion earlier in this report on reporting rates, it is likely that the 117 SAE reports for the first half of 2015 represent **11,700 actual serious events** at a 1% reporting rate. If the reporting rate is closer to 10%, these serious reports would represent **1,170 actual serious events**.

CV & CAEFISS Combined

To get a sense of the overall adverse events and adverse reactions occurring in Canada, the following table combines the data from the Q1 and Q2 government issued reports for each database. It also interprets the data for both a 1% and a 10% reporting rate to give numbers of ACTUAL events or reactions occurring. It also gives a yearly estimate based on the most recent data.

CV & CAEFISS Combined
AR +AE Reports: Q1 & Q2 2015

	AR/AE	Serious	Actual AR/AE*		Actual Serious*	
	# rpts	# rpts	@1%	@10%	@1%	@10%
CV	400	162	40,000	4000	16,200	1,620
CAEFISS	1240	117	124,000	12,400	11,700	1,170
6 month Totals	1640	279	164,000	16,400	27,900	2,790
Estimated 1 year Totals	3280	558	328,000	32,800	55,800	5,580

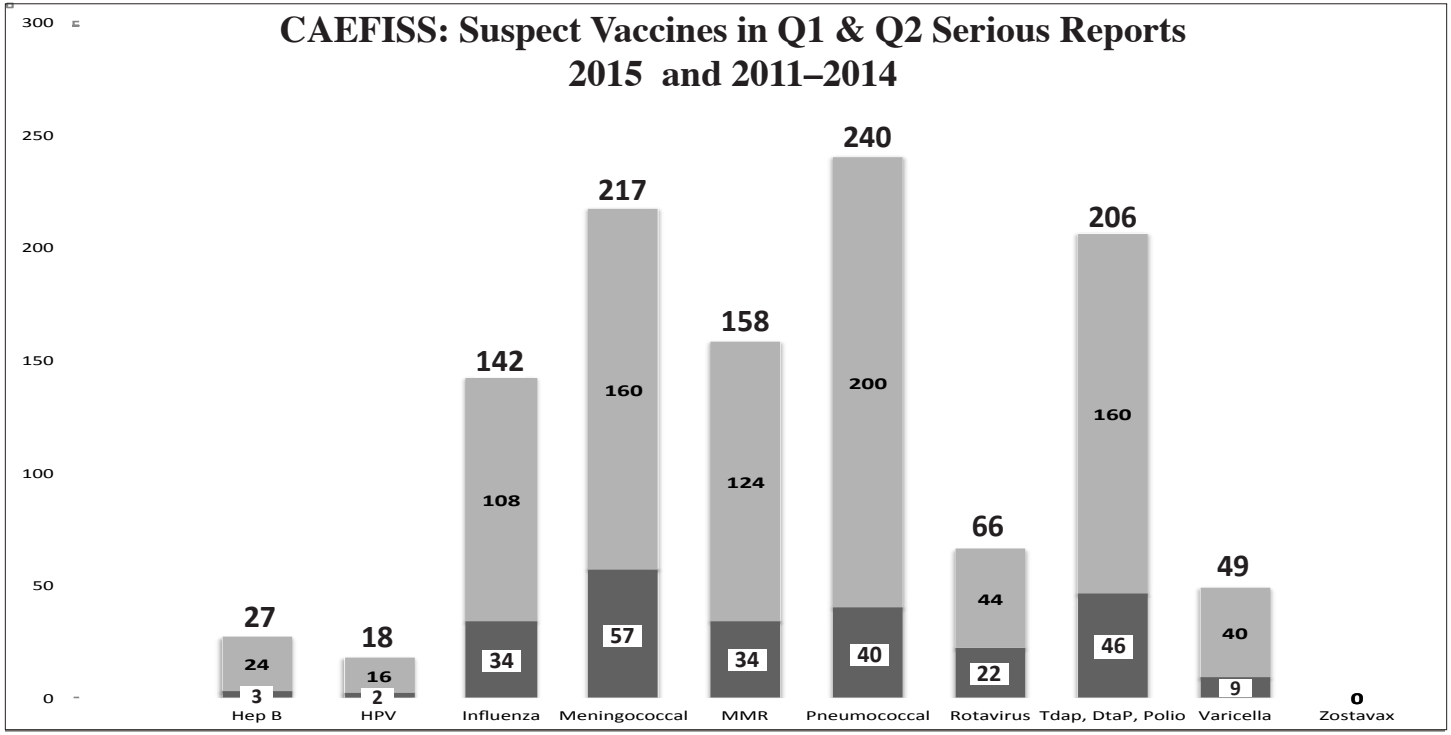
For comparison: Annual Traffic Collisons (2013)	All injuries 165,306	Serious injuries 10,315

* **1% & 10% Reporting Rates:** See *Rare Adverse Events or Rare Reporting?* on pages 8–9

It makes a difference to see the actual numbers. Few realize that as many as 55,000 people a year could be experiencing serious injuries following vaccination. Remember the definition of a serious adverse event is one that results in death, a life threatening event, hospitalization, disability or birth defect.

Compare this to traffic accident injuries. Transport Canada reports that in 2013 there were 165,306 total injuries from traffic accidents and 10,315 serious injuries (hospital admissions for treatment or observation). Every night on the news we see reports of traffic accident injuries. This reporting does not lead

us to believe that traffic accident injuries are "rare" occurrences. **Imagine how the public perception would change if even just 500 reported serious injuries following vaccination per year were broadcast, let alone the 5,000 to 55,000 actual injuries that are likely occurring.**



CAEFISS: Suspect Vaccines

The CAEFISS Quarterly Reports have tables for the frequency of each vaccine being noted in a Serious Report for current quarters compared to the average for the previous 4 years. These numbers are charted above. 2015 numbers are at the bottom of the columns. Pneumococcal vaccines rank highest, followed by meningococcal second, all the DTaP/Tdap third, MMR fourth, Influenza fifth, Rotavirus sixth, Varicella seventh, Hep B eighth and HPV ninth.

In the CV chart on page 17, Influenza and Zostavax have the highest frequencies, followed by the DTap/polio, pneumenococcal and then meningococcal. There is no logical explanation for why there are no serious reports related to Zostavax on the CAEFISS chart above when there are 260 serious reports and 3 deaths related to this vaccine on the CV chart.

Serious Reports by Age Group

Considering that all of the types of vaccines on the suspect vaccine chart are given to babies and children, **it is not surprising that the younger the child the higher the serious adverse event rate.** In the new 2015 format CAEFISS reports only give the number of events, not the percent. Combining the number of serious events for Q1&Q2 2015, calculating the percent and comparing to the previous 4 years for the same quarters, we see the Serious Reports by age group in the table below.

The rate of serious adverse events reports for pre-school age children is increasing. In 2015, 79% of SAE reports are for children under the age of 7, compared to the 73% average in the previous 4 years. And 66% of the 2015 SAE reports are for babies under the age of 2 years, compared to a 55% average in the previous 4 years.

The 2015 Q2 Report postulates that the increase in SAEs for babies "may be due in part to the recent implementation of a new hexavalent vaccines (DTaP-IPV-HB-Hib), which typically have increased AEFI reporting rates."

The reference is to Glaxo Smith Kline's Infanrix hexa®. There are 46 SAEs in the DTaP/Tdap category for 2015. **27 of these or 59% were for Infanrix hexa.** The other 3 DTaP vaccines in that category had only 16 reports (35%) between them. Infanrix hexa with its 6 antigens and high aluminium content is a highly reactogenic vaccine as the quote from the CAEFISS report above acknowledges.

SAEs by Age Group for Q1 & Q2 Combined

Age Group	Serious Adverse Event (SAE) 2015 #, (%)	Average 2011-2014 # rpts (% total)
Unknown	0	1 (1%)
65+ years	4 (3%)	11 (10%)
18<65	11 (9.5%)	15 (14%)
7<18	11 (9.5%)	10 (9%)
2<7	15 (13%)	13 (12%)
1<2	40 (35%)	29 (27%)
0<1	36 (31%)	31 (28%)
Totals	117 (100%)	109 (100%)

Age 7 and under: 79% of SAEs
Age 2 and under: 66% of SAEs

Canada Vigilance Data Q1 & Q2 2015

In response to my enquiries, the government sent electronic files of their searches of the CV database for Q1 2015. Here is a graphic from the summary sheet from their search of All adverse reaction (AR) reports for the first 3 months of 2015.

They show 238 total adverse reaction reports. **105 or 44% were serious with 2 deaths, 1 life-threatening incident, 16 hospitalizations, 13 disabilities and 84 medically important conditions.**

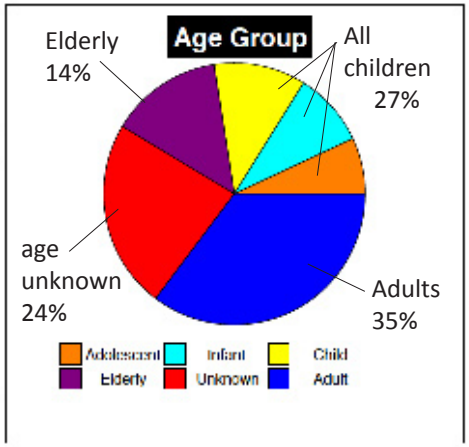
According to the Q1 and Q2 Vaccine Safety Reviews (see page 3), in the first 6 months of 2015 there were a total of 400 AR reports, of which 162 or 40% were Serious. Bexsero (meningococcal B vaccine), Zostavax (shingles vaccine) and pneumococcal (pneumonia) vaccines are mentioned as contributing to the increased number of reports.

Total No. of Reports:	238

Number of reports (percentage) with one or more reaction terms in the SOC(s) above

MedDRA V18.1

Age Group		
Infant	22	9.2 %
Child	27	11.3 %
Adolescent	16	6.7 %
Adult	84	35.3 %
Elderly	33	13.9 %
Unknown	56	23.5 %



Reason for Seriousness	
Death	2
LifeThreatening	1
Hospitalization Required	16
Disability	13
Congenital Anomaly	0
Other Medically Imp Condition	84

Patient Sex		
Female	124	52.1 %
Male	75	31.5 %
Not specified	31	13.0 %
Unknown	8	3.4 %

Serious Reports	
Yes	105
No	133

CAEFISS Data Q1 & Q2 2015

For the first half of 2015 there were a total of 1240 Adverse Event (AE) Reports on CAEFISS. This represents about 70% of the average number of reports for the first half of the previous 4 years. So **the total number of reports continues to decline.**

Looking at Serious Reports only, in the first half of 2015 there were 117 SAEs compared to an average of 109 in the first half of the last 4 years. This is a 7% increase. **As a proportion of All Reports, Serious Reports increased from 8.7% to 9.5%.**

In accordance with the discussion earlier in this report on reporting rates, it is likely that the 117 SAE reports for the first half of 2015 represent **11,700 actual serious events** at a 1% reporting rate. If the reporting rate is closer to 10%, these serious reports would represent **1,170 actual serious events**.

CV & CAEFISS Combined

To get a sense of the overall adverse events and adverse reactions occurring in Canada, the following table combines the data from the Q1 and Q2 government issued reports for each database. It also interprets the data for both a 1% and a 10% reporting rate to give numbers of ACTUAL events or reactions occurring. It also gives a yearly estimate based on the most recent data.

CV & CAEFISS Combined
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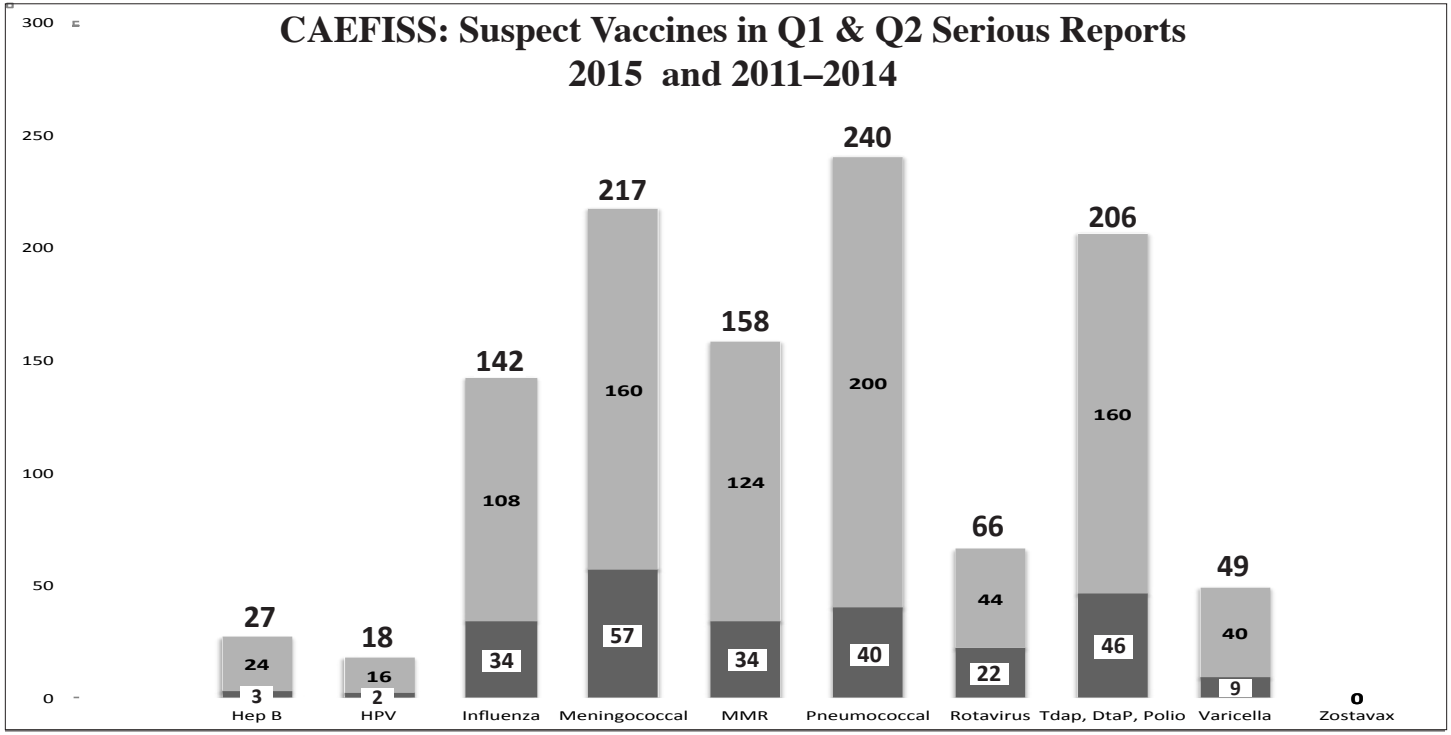

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Examining Specific Vaccines

Reviewing the CV data on Serious Adverse Reactions, three vaccines strike me as particularly important to investigate. These are Bexsero and Zostavax due to high number of serious reports and HPV due to the highest number of deaths and the severity of the serious adverse reactions.

Examining Vaccines—HPV

When considering severity of adverse reactions, the most severe is death. The 4 fatality reports all came from the manufacturer (MAH). The basic details are:

Year	Age	History	Adverse Reaction
2013	10 years old	no hospitalization	Death
2014	unknown age	no hospitalization	Death
2015	14 years old	no hospitalization	Encephalopathy
2015	19 years old	no hospitalization	Vasculitis cerebral (stroke)

The fact that none of these young women were hospitalized leads one to believe the deaths occurred unexpectedly and/or quickly. Had there been a build up of symptoms, their parents or they themselves would surely have sought medical help. The four reports are included for your examination on the following page.

It is difficult to express how distressing it is to read the HPV serious adverse reaction reports. Neil Z. Miller says it best in his book, *The Vaccine Safety Manual:*

> "By June 1, 2014, less than 8 years after the HPV vaccine was licensed in the United States, 34,700 adverse reaction reports pertaining to Gardasil were filed with the federal government—an average of 12 reports per day. Through the Freedom of Information Act, the content of these reports was made available. According to Tom Fitton of Judicial Watch, a government watchdog organization, **they "read like a catalog of horrors."** In the case reports submitted to the FDA, 165 deaths were described due to blood clots and heart disease. In addition, many of the vaccine recipients were stricken with serious and life-threatening disabilities, including Guillain-Barre syndrome, myalgia, paresthesia, loss of consciousness, seizures, convulsions, swollen body parts, chest pain, heart irregularities, kidney failure, visual disturbances, arthritis, joint pain, difficulty breathing, severe rashes, persistent vomiting, miscarriages, menstrual irregularities, reproductive system complications, genital warts, vaginal lesions and HPV infection—the main reason to vaccinate. Thousands of teenage girls and young women were rushed to the hospital for debilitating ailments following their Gardasil shots."

All of the symptoms listed in the quote above appear in the CV database reports. Although what a listing of adverse reactions cannot portray is the anguish caused by these events. Consider this example from a 2013 CV report (E2B_00045073). The suspect product is Gardasil. Imagine what the family of this 14 year old child went through as the following serious reactions described in the report unfolded:

> Apparent death of 14 minutes duration, myocardial infarction (heart attack), venticular fibrillation, implantable defibrillator inserted (pacemaker surgery), premature menopause, movement disorder, nervous system disorder, disturbance in attention and fatigue.

Now imagine what her life is like and what her future holds.

Note the above report lists **premature menopause** as an adverse reaction (in other words, sterility). This is important in light of the January 2016 HPV statement from the American College of Pediatricians noting their concern with ovarian dysfunction in relation to HPV vaccines. **Ovarian dysfunction includes premature menopause (POF) and prolonged amenorrhea (missing menstrual periods), which has been known to progress to premature menopause.**

A few other reports of note include the following:

> 11 year old: demyelination and visual field defect.
> 14 year old: Immune thrombocytopenic purpura, an autoimmune disorder characterized by excessive bleeding/bruising due to low platlett count.
> 19 year old: Guillain-Barre Syndrome (GBS)
> 16 year old: pregant when exposed, had premature infant with heart and liver problems and neonatal sepsis
> 19 year old: Activities of daily living impaired, pain in extremities
> 14 year old: weakness, loss of strength, joint pain, bone pain, menstrual disorder, visual impairment, palpitations
> 15 year old: Anaphylactic reaction, tachycardia (fast heart rate)
> 19 year old: Nephritis (kidney disease)
> Age unknown: loss of consciousness, hearing impaired, visual impairment

Many of these were reported by a physician or pharmacist. Most patients were reported as "not recovered".

Considering all the extremely serious adverse reactions that young girls and woman are at risk for when vaccinated with HPV vaccines (especially Gardasil), one would hope that at the very least they would be protected from cervical cancer.

In my searches of the CV database for 2011 through September of 2015, I found 95 Serious Reports related to HPV vaccines. As I read through these collected reports, **I found thirteen cases listing the adverse event as cervical**

Canada Vigilance
Summary of Reported Adverse Reactions

Initial Received Date: 2013-01-01 to 2013-12-31
Latest Received Date: N/A
Total Number of Reports: 16 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_00043111	0	2013-12-11	2013-12-11	MAH	1312CAN001830	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
10 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)
GARDASIL	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.18.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Initial Received Date: 2014-01-01 to 2014-12-31
Latest Received Date: N/A
Total Number of Reports: 26 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_00185326	0	2014-11-24	2014-11-24	MAH	1411CAN008895	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Unknown			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)
GARDASIL	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.18.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2016-01-21 - 01:47:31 PM
Initial Received Date: 2015-01-01 to 2015-09-30
Latest Received Date: N/A
Total Number of Reports: 10 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_00495936	1	2015-09-29	2015-09-30	MAH	1509CAN013174	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Female			Death

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_00495935
Linked	E2B_00495935

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GARDASIL	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.18.1	
Neurological symptom	v.18.1	
Vasculitis cerebral	v.18.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2016-01-21 - 01:47:31 PM
Initial Received Date: 2015-01-01 to 2015-09-30
Latest Received Date: N/A
Total Number of Reports: 10 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_00495935	0	2015-09-29	2015-09-29	MAH	1509CAN013170	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Years	Female			Death

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_00495936
Linked	E2B_00495936

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GARDASIL	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Prophylaxis, Product used for unknown indication
GARDASIL	Suspect	INJECTION	Unknown				Prophylaxis, Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.18.1	
Encephalopathy	v.18.1	

cancer. That's 13% of those serious reports! Twelve of these cases were submitted by the manufacturer in 2014 and were from published literature. Since the notation under adverse event along with "cervical carcinoma" was "drug ineffective", one can safely presume the cervical cells contained one of the HPV strains these girls/women had been inoculated against. The 13th report is from 2015 and records a 29 year old female with cervical carcinoma.

It has been known for years that if a girl or woman has already been exposed to the HPV strains contained in the vaccine prior to being vaccinated, the vaccine will not be preventative and further can actually lead to greater risk of developing cervical cancer. See 2006 FDA report (pdf page 13) and this 2010 article with many links to documents and articles.

This brief overview does little justice to the serious injuries occurring with the HPV vaccines. Even though the North American mainstream press is being censored on carrying HPV injury stories, more of the public will become aware of these dangers as doctors, researchers, parents and injured girls around the world continue speaking out.

Examining Specific Vaccines—Bexsero

Bexsero, a vaccine for meningococcal B (MenB), has only been licensed in Canada since the beginning of 2014. See *The Strange Case of Bexsero* (page 11 of the first database report) for background information on this vaccine, the licensing decisions and epidemiological studies of invasive meningococcal disease (IMD) in Canada.

Quick Facts on Bexsero:

- It targets a dreaded, though rare disease—the B strain of Meningitis
- It is not covered by publicly funded vaccine programs, nor has it been added to the child vaccine schedule, due to high cost, low disease incidence and unknown efficacy.
- Some provinces fund the vaccine for high risk groups
- It is licensed for use in children age 2 months to 17 years
- Babies under 1 year of age have the highest incidence of the disease, "yet fully 73% ...will not be affected by the adoption of this vaccine"
- Its efficacy and effectiveness have not been proven.
- It is known to have a high rate of certain adverse reactions, especially when given with other childhood vaccines.
- It is expensive.
- Like Zostavax, it is now advertised on TV.

In Europe Bexsero was licensed in 2013 for use by medical prescription only (i.e. doctors decide on a case-by-case basis). In the USA it was licensed in 2015. Following are the CDC committee recommendations:

> "The current low prevalence of disease, coupled with the fact that important data for making policy recommendations for MenB vaccines are not yet available, resulted in ACIP determining that insufficient evidence exists to make a routine public health recommendation that all adolescents be vaccinated with MenB vaccine...
>
> Why are the recommendations being modified now? Two serogroup B meningococcal vaccines were recently licensed by the Food and Drug Administration and approved for use in persons aged 10–25 years. The evidence supporting the use of MenB vaccines in adolescents and young adults was evaluated...The recommendation was designated as Category B (**recommended for individual clinical decision making**).
>
> What are the new recommendations? A MenB vaccine series may be administered to adolescents and young adults aged 16–23 years to provide short-term protection against most strains of serogroup B meningococcal disease. [with doctor discretion]
>
> The preferred age for MenB vaccination is 16–18 years."

Like Canada, the USA has not added this vaccine to the routine vaccination schedule. **However, unlike Canada who is allowing vaccination of babies, from 2 months of age, and children and adolescents for supposed "long-term protection", the USA is only recommending the use of Bexsero in times of outbreaks of Meningococcal B disease and then only for 16 to 18 year olds.** The full Canadian evaluation on Bexsero is found here. The American evaluation is found here.

Efficacy, Effectiveness and Safety

The "lack of data" that both the USA and Canadian evaluations (linked above) refer to relates to both efficacy and effectiveness of the vaccine. Efficacy is a lab measurement of the percent of vaccinees that produce antigens at certain levels. Effectiveness refers to random controlled clinical studies of the percent of vaccinees who are actually protected from acquiring the disease. The production of antigens does not necessarily protect vaccinees from the disease as we know from various disease outbreaks in vaccinated populations. The antigen testing in the manufactures literature is MATT testing which is done in a petri dish in the lab. That is the virus is subjected to the vaccine and the results are measured. This is very different from actually testing the blood of vaccinees for antigen production. This is why both evaluations say the efficacy is inferred, rather than proven. Also there is a question as to whether herd immunity is even possible with this vaccine due to waning times and the lack of efficacy and effectiveness studies. Of course the other problem is that the vaccine is not effective in babies younger than 6 months of age where the majority of meningococcal B cases occur.

The safety data is troubling as well. One assumes this is why the Americans do not recommend Bexsero for younger children and babies. Both evaluations acknowledge safety concerns, particularly high rates of pain and fever.

The Vaccine Merry-Go-Round

The history of vaccines and their role in the proliferation of bacterial meningitis is important to understand in relation to this new MenB vaccine, Bexsero. What has happened over time is that vaccines have been introduced to reduce the incidence of a certain bacterial disease, which they do. But then another bacterial disease (or a different strain of the same disease) arises to take its place in the population. So a second vaccine is developed to combat that bacteria and then another bacteria or strain becomes prominent.

After DTaP vaccines were introduced meningitis became a concern. It is still a concern as new vaccines are developed and different forms of meningitis continue to arise. **We are on the vaccine merry-go-round here.**

The Vaccine Merry-Go-Round

DTaP mass vaccination campaigns led to a rise in Hib meningitis ⇢ **Hib mass vaccination campaigns led to a rise in pneumococcal & meningococcal meningitis**

Meningitis — Inflamation of the membranes surrounding the brain & spinal cord

Viral

Bacterial

Hib disease
Haemophilus Influenza

6 encapsulated Strains
a,b,c,d,e,f
+ unencapsulated strains

Hib Vaccines for strain b
Act-Hib® & Hiberix®
Usually administered to babies and children with DTaP & Polio in
Pediacel® or Infanrix®

or with DTaP, Polio & Hep B in
Infanrix hexa®

Associated with Rise in
Type 1 diabetes, pneumococcal & meningococcal disease, and other strains of Haemophilus Influenza (a, c, d, etc)

Pneumococcal disease
Streptococcus pneumoniae

90 Strains
1, 2, 3, 4, 5, 6B, 7F, 8, 9N, etc

Pneumococcal vaccines
Pneumovax® adults
Prevnar 7® for babies & children
now replaced by
Prevnar 13®
13 strains only

Associated with Rise in
Type 1 diabetes
May "increase carriage of and diseases of the other strains"
Most reactogenic vaccine
Efficacy untested
Duration unknown

Meningcococcal disease
Neisseria meningitidis

at least **13 Strains**
A, B, C, Y, W-135,
29E, D, H, I, K, Z, etc

Meningococcal vaccines
Bexsero® strain B

Meningitec® strain C
Menjugate® strain C
NeisVac-C® strain C

Menactra® strains ACYW
Menomune® strains ACYW
Menveo® strains ACYW

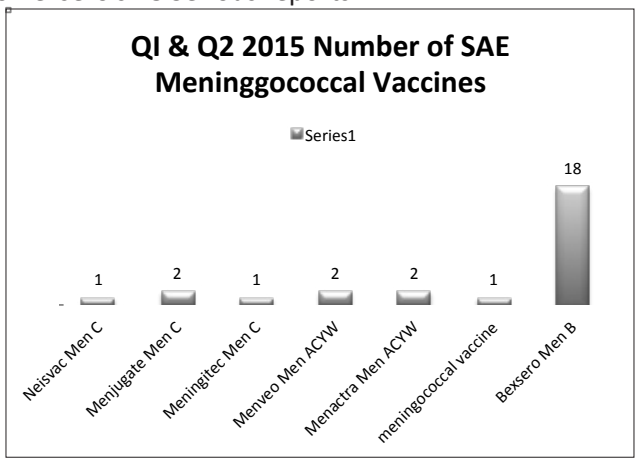
Men C mass vaccination campaigns have led to new and atypical C and B strains
B is the most virulent strain
Efficacy rates are unreliable and wane rapidly (3 years)

Based on information from the *Vaccine Safety Manual* by Neil Z. Miller and the Canadian Immunization Guide (Active Vaccines)

CV Q1 & Q2 Bexsero Serious Adverse Reaction Reports

I found 18 Serious reports for Bexsero during the first two quarters of 2015. The government found 15, however after removing the duplicates there are really only 11 SAE reports in their searches. I am presuming that my search has picked up reports that were entered on-line after the government searches or maybe "their quality control activities" removed some reports.

Comparing Bexsero to the five other meningococcal vaccines for other strains results in the chart below. It shows the other vaccines have only 9 SAEs in total compared to Bexsero's 18 Serious reports.



Note the report with no brand name (meningococcal vaccine) is likely a Men C vaccine (either single or quadrivalent); but it could also be Men B–Bexsero.

In the 18 Bexsero Serious reports, 8 of the cases fall into the correct use age group, between 2 months and 17 years old. 3 cases are of unknown age. The other 7 cases are adults, but they are all on the drug Soliris (eculizumab). Soliris is one of the most expensive drugs in the world. (In Canada the cost for a patient is more than half a million dollars annually.) It is used for treatment of two rare, but life-threatening, blood disorders. The catch with this drug is that it predisposes the recipients to meningococcal diseases. In the past they were administered Men C vaccines before starting treatment. Now that there is a Men B vaccine, Bexsero, patients are being administered this vaccine as well. The Canadian Immunization Guide (Part 4, Meningococcal vaccines, Table 3: High risk groups) says [emphasis ours]:

"Footnote 6: 4CMenB vaccine [Bexsero] is not authorized for use in those 17 years of age and older; however, **based on limited evidence and expert opinion its use is considered appropriate."**

The 8 Bexsero Serious reports for children and babies contain the following adverse reactions of note.

- 10 year old: Vaccination site redness, rash, swelling and pain
- 12 year old: Fainting, fall, skull fracture, extradural hematoma, amnesia, brain confusion
- 14 year old: Nausea, panic attack, tremor
- 11 year old: Vaccination site bruising, cellulitus, swelling, fever
- 9 year old: Dizziness, headache, fainting, vomiting, vaccination site pain
- 3 mnth old: Irritability, bleeding from the anus (from maternal exposure)
- 2 year old: Urticaria (hives, an allergic reaction)
- 2 year old: Throat pain, generalized rash

The 3 reports for unknown ages include the following serious reactions:

- No age 1: lack of strength, fatigue, chills, fever, jaundice
- No age 2: Allergic granulomatous angiitis (an autoimmune condition involving severe asthma and blood vessel inflammation)
- No age 3: Wheezing, shortness of breath

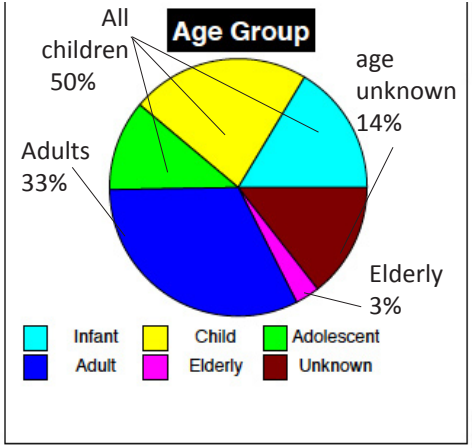
Below is the graphic from the Q1 2015 Summary Sheet for the government CV database search on Bexsero. It shows a total of 62 Bexsero-related Adverse Reactions, 15 of which were Serious. Of those serious reactions, 2 required

MedDRA V18.1

Total No. of Reports:	62

Number of reports (percentage) with one or more reaction terms in the SOC(s) above

Age Group		
Infant	10	16.13 %
Child	14	22.58 %
Adolescent	7	11.29 %
Adult	20	32.26 %
Elderly	2	3.23 %
Unknown	9	14.52 %



Reason for Seriousness	
Death	0
LifeThreatening	0
Hospitalization Required	2
Disability	0
Congenital Anomaly	0
Other Medically Imp Condition	14

Patient Sex		
Female	33	53.23 %
Male	19	30.65 %
Not specified	10	16.13 %

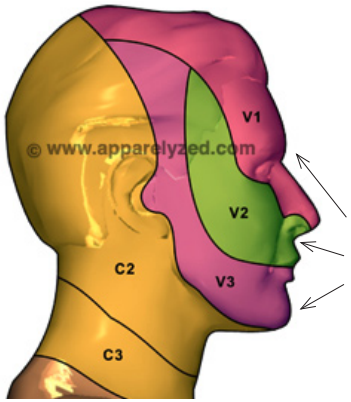
Serious Reports	
Yes	15
No	47

hospitalization and 14 where Medically Important Events that required intervention.

50% of Bexsero reports are for children of all ages. These would be children within the licensed age group of 2 months to 17 years. The other 50% of reports is made up of 14.5% (unknown age) and 35.5% (adults). I found that 30% of the adult reports listed Soliris as either a concomitant or suspect drug. So that pretty much accounts for all the adult reports except a few. If the other 20% of reports are for people who are not children or not considered high risk, this would be considered unlicensed use (or as the industry prefers to call it "off label" use) of the vaccine.

One final curious note regarding Bexsero. In the 3rd quarter (July to Sept) of 2015, a Safety Review of Bexsero **to consider the safety of use in older adults** was instigated. Reviews are announced and then when completed a Summary Safety Review is posted on the MedEffect's web site. **To date (mid-March) all of the 3rd quarter 2015 Summaries have been posted, except Bexsero. I emailed MedEffect and asked why the Bexsero safety summary wasn't posted. I have not yet received a response, nor do I expect one.** I speculate the reason the Summary has not been posted is the extended use was turned down due to the high number of adverse reaction reports for this vaccine. I could be wrong, but until we see the Summary Review we will not know.

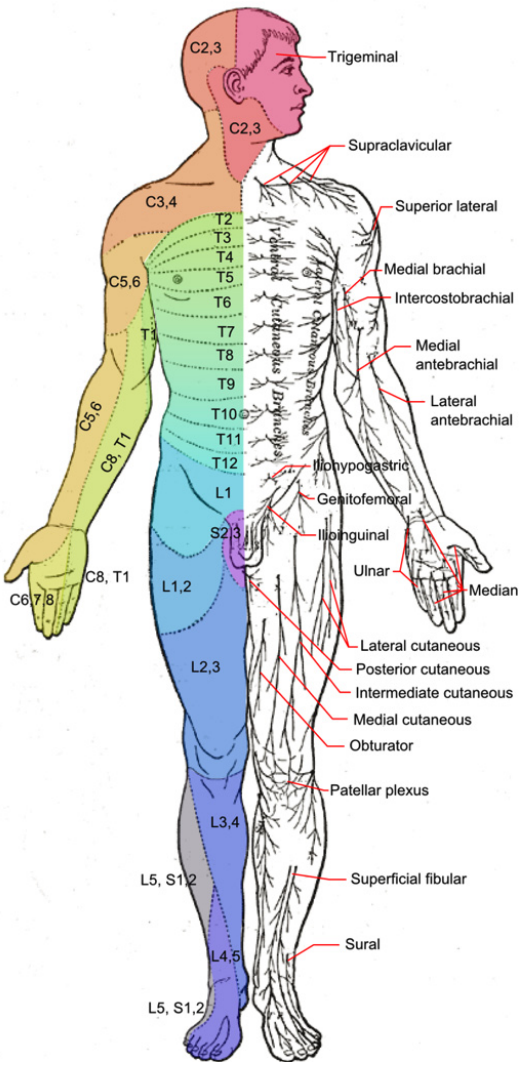
Examining Specific Vaccines—Zostavax



Trigeminal nerve divisions:
V1 - Ophthalmic
V2 - Maxillary
V3 - Mandibular (includes mouth, tongue and jaw)

Varicella-zoster virus (VZV) causes chickenpox (varicella) and shingles (herpes zoster). After a case of chicken pox (or following vaccination with the live virus vaccine for chicken pox), the virus remains latent in the body's nervous system in the spinal cord and the brain. The specific locations are the 31 pairs of ganglia of the dorsal roots in each section of the spinal cord and in the trigeminal nerve (fifth cranial nerve) in the brain.

The anatomical drawings show dermatomes (areas of the skin) related to trigeminal and spinal ganglia. The classic painful, blistered rash of shingles can occur in any of these areas. When reviewing the Zostavax adverse reaction reports, one sees many symptoms not reported as shingles (herpes zoster) *per se* that show reactivation of VZV in one or more of these locations.



If the varicella-zoster virus reactivates, shingles (also referred to as herpes zoster or HZ) occurs. The reactivation rate is variously reported as 10 to 30% in those who have had chicken pox or been vaccinated for it. Good historical data is unavailable. In Canada shingles has never been a reportable disease. Zostavax was licensed for use in Canada in 2010. An update on use was issued in 2014. It is recommended for use for 60 years of age and over, but can be administered to those in their 50's. Chicken pox was not a reportable disease for 27 years from 1959 to 1985. Varicella (chickenpox) vaccine was introduced in Canada in 2007. Today 5 provinces & 2 territories routinely vaccinate children against chicken pox, while 5 provinces & 1 territory do not.

There are many complicating and controversial factors relating to the two diseases and to the vaccine campaigns against them. A thorough paper (Schmid 2010) titled Impact of Varicella Vaccine on Varicella-Zoster Virus Dynamics attempts to untangle many of the complications. Though slightly vaccine apologetic in its conclusions, it presents much data for the discerning reader. Here's one example:

"The virus reactivates later in life in about 15 to 30% of the population

due to the waning of specific cell-mediated immunity (CMI), causing zoster, a unilateral, usually painful, vesicular rash illness. Herpes zoster is more common among the elderly and those with impaired cell-mediated immunity. Since the varicella vaccine is a live-attenuated virus that can establish latent infection in vaccine recipients, the issue of herpes zoster incidence among vaccine recipients is an important concern for the varicella vaccination program."

As vocal critic, G.S. Goldman, pointed out in a 2013 paper regarding his analytical work for the CDC on data from the Antelope Valley (AV) varicella surveillance site, there are indeed many complications to the chickenpox vaccine campaign. From the abstract:

"Varicella case reports decreased 72%, from 2834 in 1995 to 836 in 2000 at which time approximately 50% of children under 10 years of age had been vaccinated. Starting in 2000, HZ [shingles] surveillance was added to the project. By 2002, notable increases in HZ incidence rates were reported among both children and adults with a prior history of natural varicella. However, CDC authorities still claimed that no increase in HZ had occurred in any US surveillance site. The basic assumptions inherent to the varicella cost-benefit analysis ignored the significance of exogenous boosting caused by those shedding wild-type VZV. Also ignored was the morbidity associated with even rare serious events following varicella vaccination as well as the morbidity from increasing cases of HZ among adults. Vaccine efficacy declined below 80% in 2001. By 2006, because 20% of vaccinees were experiencing breakthrough varicella and vaccine-induced protection was waning, the CDC recommended a booster dose for children and, in 2007, a shingles vaccination was approved for adults aged 60 years and older. In the prelicensure era, 95% of adults experienced natural chickenpox (usually as children)–these cases were usually benign and resulted in long-term immunity. Varicella vaccination is less effective than the natural immunity that existed in prevaccine communities. **Universal varicella vaccination has not proven to be cost-effective as increased HZ morbidity has disproportionately offset cost savings associated with reductions in varicella disease.** Universal varicella vaccination has failed to provide long-term protection from VZV disease."

The Schmid 2010 paper also points out the breakthrough illness and the rise of HZ in older children in the post- vaccine era.

"The licensure and recommendation of varicella vaccine in the mid-1990s in the United States have led to dramatic declines in varicella incidence and varicella-related deaths and hospitalizations. Varicella outbreaks remain common and occur increasingly in highly vaccinated populations... Varicella vaccine is ~80 to 85% effective in preventing any varicella disease and >95% effective in preventing severe disease. Therefore, about 15 to 20% of healthy vaccinated children will develop breakthrough varicella... In 2005, 11 years after varicella vaccination commenced in the United States, **breakthrough cases in the two (high-coverage) active surveillance sites accounted for 57% (AV) and 64% (WP) of reported varicella cases**... **The observation of relatively high rates of susceptibility to breakthrough varicella (typically 20%) coupled with the observation that even very mild disease was capable of being transmitted provided two of the strongest arguments for a 2-dose schedule for children."**

So the vaccinated had higher varicella rates than the unvaccinated at these two surveillance sites. According to another study while HZ (shingles) declined 55% in children under the age of 10 in the post-vaccine era of 2000–2006 "during the same period, the incidence of **HZ among those aged 10 to 19 years increased by 63%**, from 59.5/100,000 persons to 96.7/100,000 persons."

No one denies that HZ rates are rising in the elderly. But linking it to the vaccination campaigns is clouded by the fact that some data shows the rates were rising prior to the mass chicken pox vaccination campaigns and are also rising in countries that don't have such campaigns.

Shingles Disease Incidence Rates

The Canadian Immunization Guide estimates 130,000 new cases of HZ per year with 2/3 of those cases in people age 50 or older. The CDC on USA rates says: "There are an estimated one million cases of herpes zoster in the United States annually." They break that down to incidence for all ages at 4 cases per 1000 population and for those over age 60 to 10 cases per 1000 population.

Zostavax Efficacy, Effectiveness and Cost

The studies on efficacy and effectiveness of the vaccines show low efficacy and effectiveness ranges, which decline as age increases. Also efficacy declines with length of time since vaccinated. That is waning rates are high. Following is a table that compiles the data from various trial reports and studies on Zostavax. The Efficacy rates in the table are from manufacturer pre-license trial studies: (Shingles Prevention Study and Short Term Persistence Substudy SPS & STPS).

AGE:		60-69	70-79	80+
Efficacy against HZ (lab test)				
SPS study	Avg **50%**	64%	38%	18%
SPS & STPS	Avg **49%**			
Waning Efficacy				
Health Canada	efficacy lasts 5 years			
After 7-10 yrs	Avg 21% efficacy			
After 10 years	Decreases 8% per year			

So more than a third of those in their 60's and almost two thirds of those in their 70's who are vaccinated will NOT be protected from shingles. Further as you age, your risk of getting shingles increases and the vaccine protection decreases (to 18% per cent efficacy in the chart for those 80 years old and over). As Dr. Shelley McNeil of the Canadian Center for Vaccinology in Halifax explained in a 2013 CBC interview: "A limitation of giving the vaccine for people in their 50's is that might be too early...We know that it lasts out to about five years for sure, but my main risk of course will be when I'm 70, 80, 90," McNeil said. "The earlier we give it, the higher the chance perhaps [sic] that it may not still be working by the time you're at your highest period of risk."

Canadian medical journalist, Alan Cassels explains efficacy statistics well when he asks the question: "Does the Zostavax vaccine work?"

> "**If a vaccine is about protecting you from a disease, you need to know your likelihood of getting the disease in the first place**. One study from the British Medical Journal says that for people over 50, approximately two to three people out of a thousand per year get shingles; that increases to about eight per thousand for those 70 and over. The average doctor with 1,500 patients in his care would see about three to five cases per year.
>
> A 2005 study in the New England Journal of Medicine enrolled over 38,000 people over 60 and reported that, over three years, the vaccine Zostavax "reduces the occurrence of herpes zoster by 51.3%."
>
> Wow. So if you know 100 people who got vaccinated, the vaccine would prevent half of them from getting shingles, right?
>
> Wrong. Remember, if the average doctor sees five cases a year in his practice and he manages to reduce that load by 50%, he'd only see maybe 2.5 cases per year. But how many thousands would he have to vaccinate to prevent those other 2.5 cases? A lot.
> ...The study noted there were 315 shingles cases among those vaccinated and 642 among placebo recipients, concluding that it reduced the rate of shingles by 51.3 percent. Another way this is expressed is in "1,000-person years" where the effects are examined in 1,000 people for one year. The study found that the vaccine dropped the rates of shingles per 1,000 person-years from 11.12 (those on placebo) to 5.42 (those given the vaccine).
>
> What this means is the vaccine 'helps' about 5.7 people per thousand per year (11.12 minus 5.42= 5.7). Where did the "51.3 % reduction" come from? Well, when you drop the rate from 11.12 to 5.42, that's about half the rate, or a 51.3% reduction.
>
> To summarize, here are two ways of presenting the same data:
>
> 1) "The vaccine helps five people per thousand vaccinated. Or 2) "The vaccine helps 50% of the people vaccinated."
>
> Hmmm. You can imagine which one gets the most traction with the marketers.
>
> So let's talk cost. If you have to vaccinate 1,000 people per year at $150 a shot, it would cost $150,000. That's a fair bit of money to save five people from getting shingles. In other words, the cost of avoiding shingles is about $30,000 per person per year. Does that sound like a bargain? Depends on whom you ask. If you asked Judy's friend Jane, she'd probably say that not seeing her husband in such pain is "priceless." If you ask governments to pay for the vaccine, seems they think it's too high a price to pay and it isn't covered in BC. It's not that the vaccine doesn't work; **it's that it hardly works.**"

Two European studies addressed cost effectiveness of Zostavax—one in Germany and one in Belgium. Both found that for a vaccination program **for 60 year olds to be cost effective, the price of the vaccine would have to drop 80% in Germany and 50% in Belgium based on price of €90/dose.**

We have no public access to prices in Canada, but the American CDC Vaccine price list shows Zostavax is one of the 4 most expensive vaccines on the adult vaccine list. Prices are CDC contract price in US dollars.

9-valent Gardasil HPV:	$126/dose
Bexsero (MenB):	$123/dose
Zostavax:	$117/dose
Prevenar 13	$116/dose (pneumenococcal vaccine)

It is interesting that these 4 most expensive vaccines also have high serious adverse event and/or death counts.

CV Data on Zostavax

Unlike other vaccines, Zostavax is relatively simple to search on the CV database as it is the only shingles vaccine licensed in Canada. (GSK has a rival, reportedly more effective, vaccine in trials, but it is yet to be licensed in Europe, the US or Canada.)

In my searches of the entire range of dates on the database for Zostavax, the earliest report is from October of 2010. This makes sense as it takes awhile for a vaccine to come into use after licensing. From October of 2010 until the last entry on the database in September of 2015 (5 years), there have been 404 AR reports. 202 or **50% were serious reports**. Of the 404 AR reports, **78 reports or 19% note Herpes Zoster (i.e., a case of Shingles) as an adverse event.** This

may be due to the low efficacy/effectiveness of the vaccine. The 5 years or more waning of vaccine efficacy would not yet be operating in these reports. There were 3 deaths, all in people in their 90's.

Searching the VAERS database in the US for shingles vaccine in the same time period (Oct 2010–Sept 2015). I found 15,308 Adverse Event reports, 523 of which were Serious. There were 33 death reports as follows:

Age	Count	Percent
44-65 Years	6	18.18%
65-75 Years	10	30.3%
75+ Years	12	36.36%
Unknown	5	15.15%

Oddly, the CAEFISS database in Canada has NO Serious reports for Zostavax in the last 5 years (see chart, pg 21). It does have 120 Non-Serious reports for 2011–2014 and then jumps to 119 Non-Serious reports in Q1 and Q2 of 2015. If these 239 reports are added to the 404 AR reports on the CV database the sum total of Canadian reports on Zostavax would be 643 reports. This represents not 10% of the American reports as we expect, but only 4%. Whether this reflects a failure to report Zostavax adverse events in Canada or whether fewer senior Canadians can afford to purchase or simply choose not to take this vaccine cannot be determined from the information we have access to.

Now let's look at the actual reported adverse events in the 61 Serious reports on the CV database from January through September of 2015. I believe you will see that many of the adverse events reported relate to reactivation of the herpes zoster virus. Since there is no complete reporting with follow-up we cannot tell if any of these reports indicate the first stages of shingles in these patients. The Mayo Clinic lists these as symptoms of shingles:

Skin pain, burning, numbness or tingling
Sensitivity to touch
A red rash that begins a few days after the pain
Fluid-filled blisters, Itching
Some people also experience: Fever, Headache, Sensitivity to light, Fatigue

This Harvard Medical School letter, is more complete when it explains the many presentations of shingles:

"The classic shingles symptom is a painful rash on the trunk that's limited to one or two dermatomes, areas of the skin supplied by a single nerve... Classic shingles [rash] is just one of the problems that reawakened varicella-zoster can cause. Sometimes there's pain and skin sensitivity but no rash. Arms and legs may feel weak if the nerves that control their movement are affected. If the virus is in the ophthalmic branch of the trigeminal cranial nerve, parts of the eyes and the eyelids get inflamed. Some researchers believe that up to a quarter of cases of Bell's palsy, a condition that causes facial paralysis, may be caused by varicella-zoster virus."

The Adverse Reaction reports:

• 13 reports listed vaccination site conditions including warmth, redness, swelling, pain, itch, rash, cellulitus (skin infection).

• 14 reports listed **herpes zoster** (shingles) as an adverse event. Two noted this as a vaccine failure. One noted the condition resulted in blindness, one in bilateral deafness.

• The following 26 reports list reactions that appear to be related to a reactivation of VZV virus (a shingles event) even though they are not noted as such. Only a couple appear unrelated. (UK means unknown age.)

62 yrs	Burning and rash on mucus membranes, itching, Rash, Pustular rash, Skin burning sensation
59 yrs	Paraesthesia (tingling, pins & needles sensation)
66 yrs	Facial nerve paralysis
UK	Itching generalized, Rash generalized
UK	Eye discharge, Fever, Rash maculo-papular, itchy rash
66 yrs.	Asthenia (weakness), Blister, Eye pain, Fatigue Influenza like illness, pins & needles oral & skin
62 yrs	Stroke, autoimmune disorder, nervous system disorder, balance disorder, Central nervous system lesion, Fine motor skill dysfunction, Ageusia (loss of taste), Blepharospasm (involuntary closing of the eye), Double vision, Burning sensation, Dysarthria (motor speech disorder), Dysphagia (difficulty swallowing), Ear swelling, Eye movement disorder, Eye itching & swelling, Facial pain, Headache, Hypoaesthesia (numbness), Hypoaesthesia oral & throat, Lip swelling, Pain in extremity, Paraesthesia (tingling), Rhinalgia (nose pain). Swelling face, Vision blurred
58 yrs	Diplopia (double vision), eye ptosis (eyelid drooping), Miosis (pupil constriction)
78 yes	Rheumatoid arthritis
59 yrs	Guillain-Barre syndrome, Headache, numbness, pins & needles, Tinnitus
67 yrs	Abdominal pain, Fall, Muscular weakness, Musculoskeletal disorder, Vaginal haemorrhage
68 yrs	Acne, Pruritus (itching), Lip pruritus, swollen tongue
74 yrs	Trigeminal nerve disorder, Varicella post vaccine, Eye irritation & pain, Erythema (red skin or mucus membranes), Neuralgia, Pain, Skin burning, itching, tingling, Skin lesion, Swelling, Visual impairment
UK	Allergic reaction: Angioedema (swelling of the skin & subcutaneous tissue), Chest pain, shortness of breath, Flushing, throat swelling, Palpitations & Somnolence continued for 1 month
UK	Rash, Skin reaction, Itching
81 yrs	Facial pain, Rash vesicular, skin discoloration, Skin necrosis
UK	Joint range of motion decreased, Pain in extremity

61 yrs Varicella, Abasia (speech & language disorder), Difficulty swallowing
65 yrs Asthenia (weakness), Gait disturbance, Pain in extremity
65 yrs Abasia (inability to walk), Muscle spasms, Muscle swelling & pain, Musculoskeletal stiffness
59 yrs Double vision & headache
74 yrs Hypertensive (high blood pressure) crisis, headache, chest discomfort,
50 yrs Drug ineffective, Hypersensitivity, Laryngeal disorder, Nausea, Rheumatoid arthritis, Treatment failure
70 yrs Lung infection, Rheumatoid arthritis
49 yrs Allergy to vaccine, Shortness of breath, Gait disturbance
UK Gait disturbance, Impaired driving and work ability, Muscle spasms, Pain

This extensive list shows the type of adverse reactions real people have experienced when vaccinated with Zostavax. Apparently my concerns with incidence and severity of adverse reactions to Zostavax (despite all the declarations of how safe this vaccine is) are not unfounded as this letter in the *New England Journal of Medicine* verifies:

"In his article on herpes zoster, Cohen overstates the efficacy and safety of herpes zoster vaccine in the elderly. Cohen correctly notes the efficacy of the herpes zoster vaccine in preventing infection is 38% for persons 70 years of age or older, but this is only part of the story. **For persons 80 years of age or older in the Shingles Prevention Study,[1] the herpes zoster vaccine was no better than placebo for the prevention of herpes zoster or postherpetic neuralgia but resulted in a more than a doubling in the rate of serious adverse events in the first 42 days after vaccination** (P=0.19).

A safety study mandated by the Food and Drug Administration showed a 26% increase in the rate of serious adverse events in the first 42 days after herpes zoster vaccination (P=0.16).[2,3] When the results of this safety study were combined with those of the Shingles Prevention Study, **there was a 36% increase in the rate of serious adverse events associated with the herpes zoster vaccine in persons 60 years of age or older** (P=0.01).[3,4] **The efficacy and safety of the herpes zoster vaccine in the elderly are questionable.**"

Roy E. Fried, M.D., M.H.S.
Premier Senior Care, Bethesda, MD

(Emphasis ours. Hyperlinks to the studies referenced are found in original letter at the *NEJM* hyperlink above.)

Shingles Vaccination: "You Need to Decide for Yourself"

Much of the justification for the use of the shingles vaccine at all is based on the fact that medical treatments for the serious pain accompanying shingles and especially postherpetic neuralgia (PHN) are often ineffective. An article in *Canadian Family Physician*, the journal of the College of Family Physicians of Canada, explains treatment problems to doctors as follows:

"Typically, 10% of those with HZ will experience persistent pain 1 month following rash onset; in those 60 years of age and older, this can increase to 50% of HZ cases, despite treatment.[4–6] Half of patients who continue to suffer after 1 year will continue to have unrelieved pain, which will inevitably affect quality of life.[7]

Postherpetic neuralgia is notoriously difficult and sometimes even impossible to treat, despite the use of strong analgesics such as opioids. Pathologic evidence suggests that VZV can cause permanent peripheral and central nervous system damage,[7] destroying sites of intrinsic pain inhibitory mechanisms where analgesics act; as a result, patients are left inadequately relieved by, or indeed refractory to, all drugs for pain. Antiviral medications, even when initiated within 72 hours of onset, are only marginally effective for the prevention of PHN.[8]"

Unfortunately the medical industry refuses to acknowledge the highly successful use of Vitamin C in treating shingles. In this 2013 article *Vitamin C, Shingles, and Vaccination, Opinion by Thomas E. Levy, MD, JD*, we learn that vitamin C has proven highly successful in the treatment of shingles. Excerpts from the article:

"The pharmaceutical industry, and many doctors, appear to be making great efforts to get as many people as possible vaccinated against shingles. Even if such an intervention was highly effective in preventing shingles, which certainly has not been shown to be the case, the information below should make it clear that such vaccinations are unnecessary. The side effects that would be suffered by a significant number of individuals need never occur in the first place. The real problem is that what is discussed below generates relatively little income for anybody in the health care industry. **Regardless, you need to decide for yourself.**

The clinical response of shingles to vitamin C therapy is decidedly different from its response to traditional therapies. While there are not many reports in the literature on vitamin C and shingles, the studies that do exist are striking. Frederick Klenner, MD, who pioneered the effective use of vitamin C in a wide variety of infections and toxin exposures, published the results of his vitamin C therapy on eight patients with shingles. He gave 2,000 to 3,000 mg of vitamin C by injection every 12 hours, supplemented by 1,000 mg in fruit juice by mouth every two hours. In seven of the eight patients treated in this manner, complete pain relief was reported within two hours of the first vitamin C injection. All patients received a total of five to seven vitamin C injections. Having had shingles myself years before I knew of the efficacy of vitamin C therapy, I can assert that this is nothing short of a stunning result on what is usually a painful and debilitating disease.

...Even before Dr. Klenner's observations were published, another researcher reported results just as astounding when measured against today's mainstream therapies. Dainow (1943) reported success with 14 shingles patients receiving vitamin C injections. **In another study, complete resolution of shingles outbreaks was reported in 327 of 327 patients receiving vitamin C injections within the first 72 hours** (Zureick, 1950). While all of this data on vitamin C and shingles is quite old, there is an internal consistency among the report in how the patients responded.

Until further clinical trials are conducted, these results stand. They clearly show that vitamin C should be an integral part of any therapeutic approach used on a patient presenting with shingles."

The article continues with minimum recommended dosages and a biochemical explanation of why vitamin C is "therapeutically effective in resolving many infections" and contains a list of references. Also see the Orthomolecular Medicine web site for more information and links.

I'm in my early seventies and I know what I would do if I were unfortunate enough to be one of the 5.5% of people in my age group who acquire shingles. I'd trot off to my local naturopathic doctor for vitamin C treatments. But that's just me. **You must decide for yourself.**

Safe, Effective and Necessary?

The strategy concerning vaccination programs seems to be based more on marketing than on science. Public perception is managed by public health officials and media prating the mantra that all vaccines are "safe and effective". No caveats to this statement are offered. No one says vaccines are not safe for all. No one says vaccines are not effective for all. No one even mentions the increasing chronic illness among children. And no one ever asks if all these vaccines are necessary. The licenses for new vaccines just continue to be churned out.

Independent medical researchers who publish studies that refute the *safe-and-effective* mantra are abused and discredited. Yes, we can start with Wakefield who identified a new gut disorder in autistic children. But the examples abound. We also see whistleblowers coming forward from CDC and Merck discrediting the science and the actions of industry-captured regulators.

Three recent examples are of particular interest as they relate to concerns we have expressed in this report. First we have the example of Dr. Judy Mikovits, PhD:

"In 2011, she made the discovery that destroyed her career. She found that at least 30% of our vaccines are contaminated with gammaretroviruses. Not only is this contamination associated with autism and chronic fatigue syndrome, it is also associated with Parkinson's, Lou Gehrig's disease, and Alzheimer's."

As she says in her interview in 2015 after a gag-order was lifted, the work of other scientists confirms her work; but the "mistake" she made was going public with her findings.

Then there is the recent case of Judy Wilyman and her PhD thesis: *A Critical Analysis of the Australian's Government's Rationale for Its Vaccination Policy;* From the abstract:

It is important that independent research is carried out to assess whether all the vaccines being recommended today are safe, effective and necessary for the protection of the community. It is also important to have comprehensive evidence that it is safe to combine multiple vaccines in the developing bodies of infants. The framework for undone science is used to analyse the Australian government's claim that the benefits of vaccines far outweigh the risks. Whilst the government claims serious adverse events to vaccines are rare this is not supported by adequate scientific evidence due to the shortcomings in clinical trials and longterm surveillance of health outcomes of recipients... **This investigation demonstrates that not all vaccines have been demonstrated to be safe, effective or necessary. It also concludes that the government's claim that the benefits of vaccines far outweigh the risks cannot be sustained due to the gaps in the scientific knowledge resulting from unfunded research and the inadequate monitoring of adverse events after vaccination.**

And finally the recent case of a paper by Canadian and Israeli scientists on the toxic effects of aluminum in Garasil vaccine: *Behavioral abnormalities in young female mice following administration of aluminum adjuvants and the human papillomavirus (HPV) vaccine Gardasil* From the abstract:

Vaccine adjuvants and vaccines may induce autoimmune and inflammatory manifestations in susceptible individuals. To date most human vaccine trials utilize aluminum (Al) adjuvants as placebos despite much evidence showing that Al in vaccine-relevant exposures can be toxic to humans and animals. We sought to evaluate the effects of Al adjuvant and the HPV vaccine Gardasil versus the true placebo on behavioral and inflammatory parameters in young female mice...**It appears that Gardasil via its Al [aluminum] adjuvant and HPV antigens has the ability to trigger neuroinflammation and autoimmune reactions, further leading to behavioral changes.**

Within weeks of publication, the paper was retracted by the editor of the journal *Vaccine*. "Irregularities" were cited.

As the evidence mounts, the public and parents in particular are becoming less tractable. Falling coverage rates show this. It was a great strategy...save the public from suffering illness, cut government health care costs and watch the pharmaceutical industry rake in profits: a win, win, win! There is just one problem. Perhaps Winston Churchill said it best:

"However beautiful the strategy,
you should occasionally look at the results."

Part 3: Improvements to Canadian Systems

If we are truly serious about public safety, tracking adverse events and providing the public with easily accessible information to inform their decision-making, changes need to be made to the current system of adverse event tracking and dissemination of adverse events information. However, given the push to make vaccinations seem mandatory, one wonders whether the government and medical industry is truly committed to tracking adverse events following vaccinations or promoting informed consent.

We recommend the following changes to improve vaccine safety.

A. Combine All Vaccine-related Adverse Event Reports on One Database

All of the previous discussion affirms that the only adverse events database to which Canadians have access does not function in any useful way, provides only a portion of adverse event data, and is lacking in report details.

We can only reiterate the recommendation in our original report that **all existing vaccine data be moved to the CAEFISS database and that all future data be reported there as well. Then a complete adverse events database could be made accessible to the Canadian public. And post-market adverse events could in truth be transparently monitored and used by the public in decision making.**

B. A number of other steps need to be taken to assure vaccine safety and protect the public. This is a summary of suggestions from other VCC reports found on our website.

1) **Mandatory reporting of all vaccine-related adverse events** needs to be instituted for those administering vaccines. All medical professionals, and doctors particularly, need to be encouraged—not discouraged—to report adverse events.
2) **Medical professionals need to receive formal training** to diagnose and treat vaccine injury.
3) **Canada needs to implement a compensation program** for all vaccine-related injury. It is shameful and unjust that Canada is the only major western country (except Russia) that does not have such a program.
4) **Mandatory registration of all clinical trials**, regardless of outcomes, needs to be imposed on manufacturers and researchers. (See AllTrials.net)
5) **Rigorous, evidence-based, long-term clinical safety trials need to be developed and implemented by government to assure Canadians of the safety of vaccines.** These trials necessarily need to examine the safety of giving multiple vaccines, determine whether unvaccinated populations have better long-term health outcomes than vaccinated populations. Proper scientific principles must be observed.
6) All levels of government must substantiate and adhere to the Constitutional rights and freedoms of citizens. Under these constitutionally guaranteed rights and freedoms, vaccination like other medical procedures is voluntary and should not be purported otherwise.

C. Informed Consent Ethic Must Be Adhered To

All medical procedures have risk. All Canadians have the right of informed consent to medical risk-taking. The principle of informed consent includes the right to not consent. In legal terms, informed consent cannot be based on fraud or coercion. This is why withholding certain information or disseminating other information—that is, at best, not scientifically defensible or, at worst, untrue—violates the legal principles of informed consent. Therefore the Canadian public deserves to have access to complete, defensible and up-to-date vaccine information to establish their informed consent to vaccination.

D. Disease Incidence Information

Just as health product consumers need data on adverse events in order to make informed decisions regarding medical risk, they also require information on disease incidence. As Alan Cassels said in his article on Zostavax:

"If a vaccine is about protection from a disease, consumers need to know how likely they are to get the disease in the first place."

This basic question is not addressed on any of the public health sites in Canada where the risk and benefit of specific vaccines or vaccination in general is discussed. The dangers of a disease are stated but not the risk of acquiring it. Similarly, the benefits of vaccination are stated, but little attention is paid to the risks.

Canada needs to review their national disease incidence reporting and release current and complete data to the public. Most provinces have disease incidence data on-line, broken down by regions or school districts. If the public were aware of this they could access their local data for decision-making. **Health professionals must apprise the public of the location of disease incidence data or provide that data to them.**

E. The public needs to be informed of the following resources to aid in their decision-making process:

Product Monographs

Vaccine product monographs can be found on-line by searching for the vaccine by name. The public can also search on the Canadian Drug Products database that has entries now for vaccines and their product monographs. The product monograph gives vaccine ingredients and pre-market adverse events information from clinical trials run by the manufacturer to obtain licensing of

the product. The surveillance databases (the main subject of this report) are supposed to make the public aware of the post-market adverse events after the products are in broad use. In order to access pre-market and post-market adverse event data, the public must know the brand name of the vaccine.

Those who administer vaccines must give their clients the name of the vaccine they intend to use and apprise them of both pre-market and post-market adverse events information to fulfill informed consent ethics.

2) Clinical Definitions of Adverse Events

To truly understand what is being reported in adverse event reports, the Canadian reference document for medical professionals is eye-opening. It is named ***Adverse Events following Immunization: Interpretation and Clinical Definitions*** and can be found on-line (just search its name).

I cannot stress enough what a valuable document this is. The table of contents in this pdf has active links to each adverse reaction. The information under each reaction includes a description of the event, when to report (reporting criteria), and implications which often describe why the reaction is occurring and always state whether further vaccination with the same vaccine is advisable.

The first type of reactions discussed are local reactions at the injection site. These reactions are always mentioned to parents as being expected and of little concern. However, **both minor and major reactions are listed under this heading**. Here is an excerpt on a Major Reaction at the Injection Site:

4.2. Major Reactions

4.2.1. Arthus Reaction

An Arthus reaction is a large, localized reaction characterized by pain, swelling, induration and edema. It usually begins within 48 hours following immunization and develops gradually over a period of hours. The reaction is due to circulating antigen-antibody complexes formed when there is a large amount of circulating antibodies prior to injection of the antigen. This results in massive swelling at the injection site that may involve the entire limb.

If a large local reaction occurs with the initial dose of vaccine in an infant younger than 4 months, **it is probably due to high levels of maternal antibodies in the child's blood.** Arthus reactions may be seen with too frequent boosters of tetanus-containing vaccines, and they have been observed following repeat doses of pneumococcal polysaccharide vaccine after short intervals.

Manage arthus reactions with cold compresses to the affected limb, acetaminophen and limb elevation. Most arthus reactions resolve within one week.

Reporting Criteria: Onset within 48 hours of immunization; AND Swelling extends past the nearest joint.

Implications:

If the reaction occurs with the initial dose in the primary infant series in a child younger than 6 months, **deferral of subsequent doses of the same vaccine for several months may be recommended** to wait for a decline of maternally acquired antibodies. If the child will be younger than 6 months when the second dose is due, this should be deferred until the child is 6 months; the third dose should be given 2 months later. Deferral is unnecessary if the next dose is due when the child is 6 months of age because circulating maternal antibodies will be greatly reduced.

If an arthus reaction occurs with a tetanus-containing booster, future boosters can be spaced at longer intervals and anti-toxin levels monitored to determine when boosting is needed.

Maternal circulating antibodies, you say? My question is why are we injecting babies and causing reactions if they already have maternal circulating anti-bodies against the disease we are vaccinating for? We should be testing for these anti-bodies before vaccinating. Further I wonder how many vaccinators or parents are aware that if the swelling occurs past the first joint in babies under 6 months that deferral should be recommended for several months.

Generally speaking, the Guidelines explain that the **reporting period for reactions to live attenuated vaccines is up to 6 weeks** and **for inactivated vaccines 1 week.** Again, I wonder how many parents are told to watch for adverse vaccines to live attenuated vaccines for 6 weeks following vaccination. Also of note are exceptions to this general reporting criteria for some serious adverse events with much longer reporting windows.

Recommendation: This document should be a mandatory reference document for pharmacists, public health nurses and physicians who are administering vaccinations. Like the product monographs, this reference document should also be made available to or made known to the public.

Final Recommendations:

Public Health is far too important an issue to blow with the winds of political or corporate agendas.

- Canada needs to review and revise their policies and information portals regarding vaccination information.
- A more scientifically rigourous and transparent approach should be adopted for tracking and assessing vaccine safety and for routinely collecting and disseminating all vaccine-related data.
- Routine data reporting from health professionals should be mandated.
- A compensation plan for all vaccine-related injuries should be developed and implemented