

AEFI compensation programmes

In country preparedness, feasibility, resource availability and
communication

ADVAC Alumni meeting
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Eve Dubé PhD

Centre de recherche du CHU de Québec – Université Laval

Institut national de santé publique du Québec

 @DubeEve

Disclosure



"I'm a social scientist, Michael. That means I can't explain electricity or anything like that, but if you ever want to know about people I'm your man."

Context

- Vaccines are very safe and effective
- Most adverse events following immunization (AEFIs) are mild and resolve quickly and completely (e.g., fever, swelling at the injection site, rashes, etc.).
- In rare instance, however, serious adverse events can occur regardless of proper design, manufacture and delivery
 - 2.6 cases of rare **bleeding thrombocytopenic purpura** per 100,000 **MMR** doses*
 - 1-2 additional **GBS cases** per million **flu vaccine** doses administered**
 - 1 case of **vaccine-associated paralytic polio** per 2.7 million doses of **OPV*****

*Mantadakis et al. (2010) in Omer, Betsch & Leask Nature (2019); **<https://www.cdc.gov/vaccinesafety/concerns/guillain-barre-syndrome.htm>

*** Ochmann and Roser (2017) Polio

Context



- At a population level, these rare risks **are far outweighed** by the benefits of high uptake of vaccination.
- However, in rare instances, an individual will suffer from significant consequences for the benefit of others
 - This can be anticipated though not necessarily predicted at the individual level

Vaccine injury are serious AEFIs: life-threatening, requires hospitalization, results in persistent or significant disability / incapacity, results in congenital anomaly or birth defect (WHO, Global Manual on Surveillance of Adverse Events Following

Typical approaches toward ‘vaccine injury’

Individuals who experience an AEFI may:

1. Bear the costs associated with their injuries by themselves
2. Have access to publicly-funded health and social programs that cover healthcare and disability costs (partially)
3. Seek compensation through litigation against private-sector actors (i.e., the vaccine manufacturers)
4. Seek compensation from drug adverse events programs that include vaccines
5. Seek compensation from publicly supported systems, or Vaccine Injury Compensation Programs (VIC Programs)

Vaccine Injury Compensation Programs (VIC)

- VIC Programs are ‘no-fault’ compensation schemes in which governments compensate individuals who are harmed by properly manufactured vaccines
- AEFIs
- Injuries due to vaccine misadministration (e.g., shoulder injuries due to unintentional injection of vaccine into tissues under the deltoid muscle)
- Injuries due to other vaccination errors / misconduct

Samoan nurses jailed over deaths of two babies who were given incorrectly mixed vaccines

Pacific Beat

Updated 2 Aug 2019, 3:30am

Two senior Samoan nurses have each been sentenced to at least five years in jail after they incorrectly mixed and administered vaccinations that caused the death of two infant children.

The decision was handed down after the nurses, Lusa Emo Tauvale and Leutogi Te'o, pleaded guilty



Fig. 1. Countries and provinces that have introduced vaccine-injury compensation schemes (including year of introduction)



UK, United Kingdom of Great Britain and Northern Ireland; USA, United States of America.

Greater use of
mandatory
immunization
≠
Greater use of
VIC

Harmon S. & MacDonald N. National immunization programme development and vaccine legislation: *Vaccine*. 2019; 37(21): 7527-9

Vaccination Not Mandatory	Vaccination Mandatory
Austria (1973)	France (1963)
Denmark (1972)	Hungary (2005)
Finland (1984)	Italy (1992)
Germany (1961)	Republic of Korea (1994)
Iceland (2001)	Slovenia (2004)
Japan (1970)	Taiwan (1988)
New Zealand (1974)	United States (1988)
Norway (1995)	
Quebec (1985)	
Sweden (1978)	
Switzerland (1970)	
Taiwan (1988) China (2005)	
United Kingdom (1979)	

Attwell K, Drislane S, Leask J. Mandatory vaccination and no fault vaccine injury compensation schemes: *Vaccine*. 2019;37(21):2843-8.

VIC programs

- The reasons why jurisdictions have implemented VIC Programs are diverse
- There is considerable variability in:
 - Who is eligible
 - Which vaccines are covered
 - How decision are made for compensation
 - How funds are sourced and allocated

VIC Programs

Administration	- Most are enacted and run by government (at national or subnational levels)
Funding	- National, state or municipal treasuries - Manufacturers' levy - Vaccine tax
Eligibility	- Only mandatory vaccines - Only vaccines recommended by public health - All licensed vaccines
Standard of Proof	- "Balance of probabilities", i.e. more evidence than not that a vaccine caused the injury - Probable cause - "Preponderant probability"

The process is similar in most jurisdictions



Threshold injury or disability criteria to be met before making a claim



Initial revision by an administrative body for initial eligibility and compensation decisions



Revision by external review committee if a claim is deemed complex or contentious



Formalized appeal process for claimants



Prioritization of timely resolution of claims

Elements of compensation

- Lump sum

Or

- Reimbursement proportional to the severity of vaccine injury, including:
 - Unreimbursed medical costs
 - Disability pension
 - Noneconomic loss, including pain and suffering
 - Death benefits
 - Compensation to family
 - Reasonable legal costs (in UK for both successful and unsuccessful claimants)

Litigation rights

- In most countries, claimants can seek either damages through the courts or a compensation through the program, not both
- Other countries adjust compensation payments if damage have been received through the courts

Quebec VIC Established in 1987



VIC in Quebec

- In 1979, a 5 year-old girl, Nathalie Lapierre, developed viral encephalitis shortly after measles vaccination and was left severely disabled
- Her parents brought an action against the Government of Quebec for damages. The Supreme Court of Canada concluded that:
 - There was evidence of a causal link between receipt of vaccine, encephalitis and subsequent disability BUT
 - Absence of any fault on the part of the Province (or the administering nurse)
 - **No liability without proven fault and no legislation requiring that compensation be paid in such circumstances**
 - **It was recognised, however, that the situation was unjust for this young girl**

VIC in Quebec

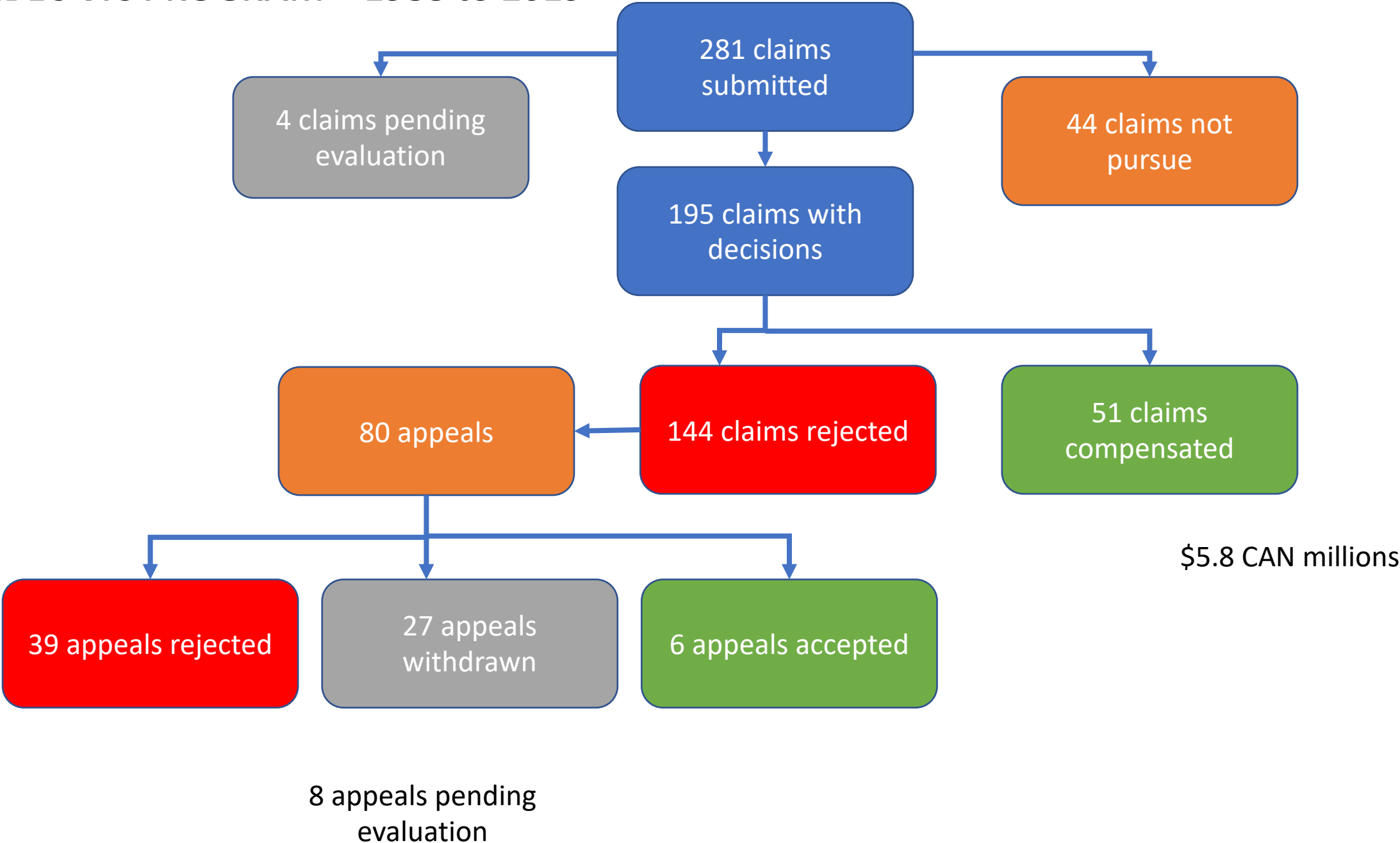
- The case was highly publicized and the Government of Quebec provided some support to the family
- In 1985, Quebec introduced its VIC Program
- A Regulation specific to this program was adopted in November 1987, and the first claims for compensation were filed the following year.

VIC in Quebec

- Voluntary vaccination with vaccines or immunoglobulins
- The vaccination must have taken place in Quebec
- The claim form must be filed within 3 years of the injury
- The claim is reviewed by an external committee of experts in vaccinology who:
 - (1) Assess the existence of a causal link between the injury sustained and the vaccination
 - (2) Assess the percentage of permanent impairment to the victim's physical or mental integrity, and other elements required regarding compensation.

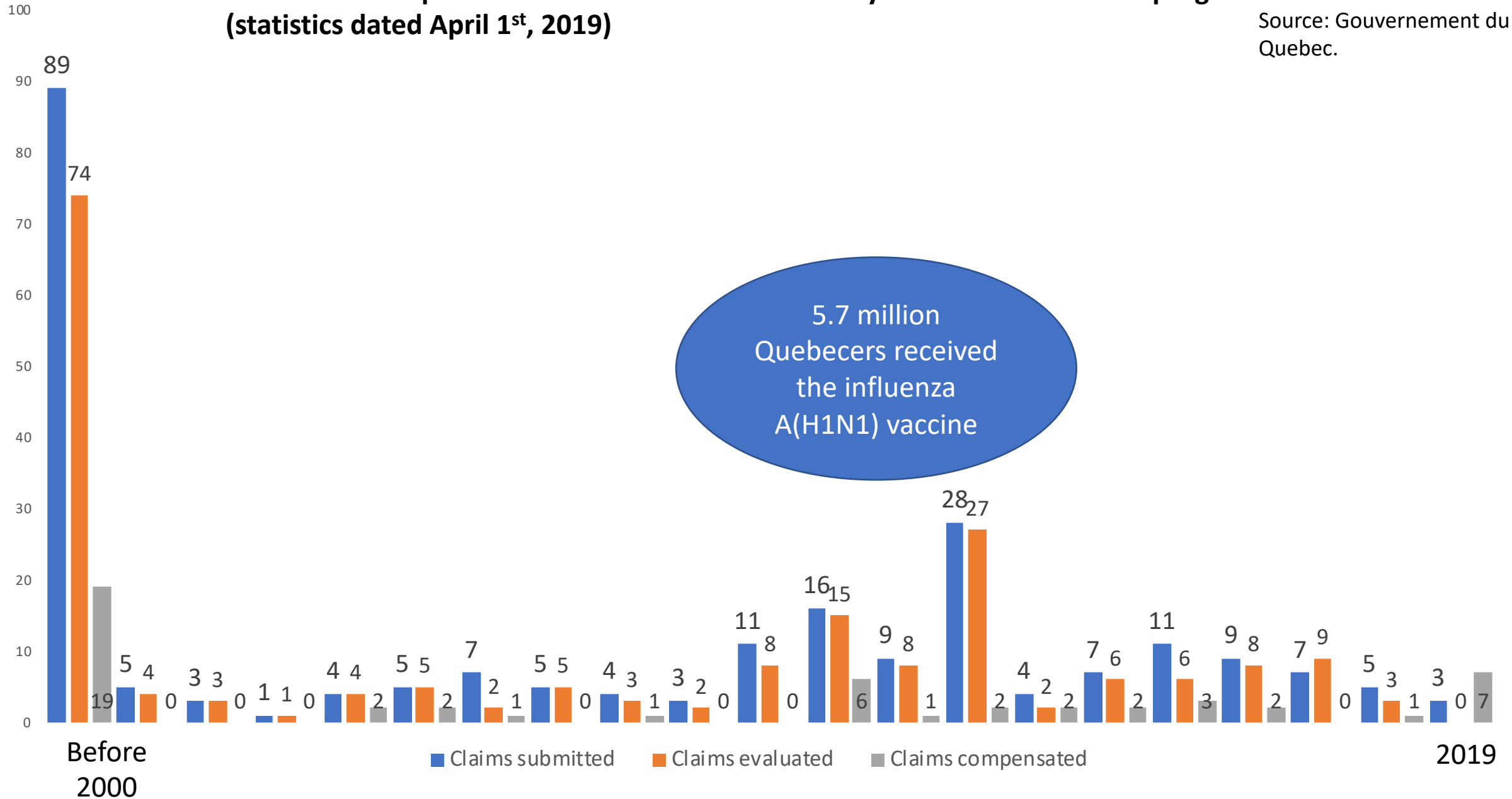
INFORMATION RELATED TO AN INDEMNIFICATION CLAIM VACCINE INJURY COMPENSATION PROGRAM (Programme d'indemnisation des victimes d'une vaccination) (To be completed by the claimant or the claimant's representative)	
1. IDENTITY AND CONTACT INFORMATION FOR THE PRESUMED VICTIM	
LAST NAME:	FIRST NAME:
DATE OF BIRTH:	PLACE OF BIRTH:
SEX: <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE	CIVIL STATUS:
HEALTH INSURANCE NO.:	
ADDRESS:	
TOWN:	PROVINCE:
POSTAL CODE:	
OFFICE PHONE:	
HOME PHONE:	
OTHER:	
2. IDENTITY AND CONTACT INFORMATION FOR THE AUTHORIZED REPRESENTATIVE	
N.B.: Complete only if the presumed victim is a minor, deceased, or unable to pursue the claim themselves.	
LAST NAME:	FIRST NAME:
SEX: <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE	
ADDRESS:	
TOWN:	PROVINCE:
POSTAL CODE:	
OFFICE PHONE:	
HOME PHONE:	
OTHER:	
TITLE OF AUTHORIZED REPRESENTATIVE	
<input type="checkbox"/> FATHER <input type="checkbox"/> MOTHER <input type="checkbox"/> TUTOR	
<input type="checkbox"/> CURATOR <input type="checkbox"/> EXECUTOR	
<input type="checkbox"/> LAWYER <input type="checkbox"/> LEGAL ADVISOR	
<input type="checkbox"/> OTHER (SPECIFY)	
N.B.: Proof of authority to act in this capacity must be attached if the representative is not the father or mother.	
3. LANGUAGE OF CORRESPONDENCE	
<input type="checkbox"/> FRENCH <input type="checkbox"/> ENGLISH	
4. RELEVANT FACTS	
<input checked="" type="checkbox"/> Date of immunization:	
<input checked="" type="checkbox"/> Name(s) of the product(s) involved:	
For which disease(s):	
<input checked="" type="checkbox"/> Location where immunization occurred (private doctor's office, CLSC, hospital, or elsewhere):	
<input checked="" type="checkbox"/> Name (if known) of the individual who administered the vaccine:	
<input checked="" type="checkbox"/> Date on which signs and symptoms possibly related to this immunization appeared:	

QUEBEC VIC PROGRAM – 1988 to 2019



Number of compensation claims submitted annually since the start of the program (statistics dated April 1st, 2019)

Source: Gouvernement du Quebec.



VIC in Quebec - Impact

- When a claim is accepted, the amount of compensation is determined using earnings and medical costs.
- Amounts are calculated according to the rules and regulations prescribed in the Automobile Insurance Act and are identical to those awarded in case of an automobile accident.

Each year, ~2 millions of Quebecers are vaccinated against flu and ~100,000 children received between 3-5 different vaccines

Less than 0.0001% of vaccination result in claims to VIC

VIC claims are used in vaccine safety monitoring

Arguments
supporting
VIC
programs

Biological

Ethical

Legal

Practical

Arguments against VIC



Costs



Difficulties in causality assessment



Decrease in public trust



Fuel for the anti-vaccine movement



Does VIC increase vaccine hesitancy?

- Anecdotal evidence of VIC used by 'anti-vaccine' groups as a 'proof' that vaccines are unsafe
- Lack of empirical data on the issue
 - VIC programs are not well-known by the public
- Importance of communication
- Importance of clear criteria for compensation



Conclusion

- The experience in the 19 jurisdictions with VIC programs indicates that costs are both manageable and predictable
 - 17/19 are in high-income countries
- Strong public health ethical justification for the implementation of VIC, especially in the context of mandatory immunization
 - Other means to compensate for vaccine injuries (e.g. publicly-funded healthcare system)
 - Other priorities around immunization
- Comprehensive global audit should be undertaken to better understand how vaccine legislation and regulation promote/undermine immunization

Thanks for
your
attention!

A STUDY LINKING AUTISM TO CHILDHOOD VACCINATIONS HAS NOT ONLY BEEN DEBUNKED, BUT IT IS AN "ELABORATE FRAUD." WE TRUST THAT THIS ENDS THE MATTER.



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