AEFI compensation programmes

In country preparedness, feasibility, resource availability and communication

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“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***

*** 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 Immunization)
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

Fig. 1. Countries and provinces that have introduced vaccine-injury compensation schemes (including year of introduction).
<table>
<thead>
<tr>
<th>Vaccination Not Mandatory</th>
<th>Vaccination Mandatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria (1973)</td>
<td>France (1963)</td>
</tr>
<tr>
<td>Denmark (1972)</td>
<td>Hungary (2005)</td>
</tr>
<tr>
<td>Finland (1984)</td>
<td>Italy (1992)</td>
</tr>
<tr>
<td>Norway (1995)</td>
<td></td>
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<tr>
<td>Quebec (1985)</td>
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<td>Sweden (1978)</td>
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<td>Switzerland (1970)</td>
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<td>Taiwan (1988)</td>
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<td>China (2005)</td>
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</tbody>
</table>


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

<table>
<thead>
<tr>
<th><strong>Administration</strong></th>
<th>Most are enacted and run by government (at national or subnational levels)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Funding</strong></td>
<td>National, state or municipal treasuries</td>
</tr>
<tr>
<td></td>
<td>Manufacturers’ levy</td>
</tr>
<tr>
<td></td>
<td>Vaccine tax</td>
</tr>
<tr>
<td><strong>Eligibility</strong></td>
<td>Only mandatory vaccines</td>
</tr>
<tr>
<td></td>
<td>Only vaccines recommended by public health</td>
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<td></td>
<td>All licensed vaccines</td>
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<tr>
<td><strong>Standard of Proof</strong></td>
<td>“Balance of probabilities”, i.e. more evidence than not that a vaccine caused the injury</td>
</tr>
<tr>
<td></td>
<td>Probable cause</td>
</tr>
<tr>
<td></td>
<td>“Preponderant probability”</td>
</tr>
</tbody>
</table>

The process is similar in most jurisdictions.

<table>
<thead>
<tr>
<th>Process Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Threshold injury or disability criteria</td>
<td>to be met before making a claim</td>
</tr>
<tr>
<td>Initial revision</td>
<td>by an administrative body for initial eligibility and compensation decisions</td>
</tr>
<tr>
<td>Revision</td>
<td>by external review committee if a claim is deemed complex or contentious</td>
</tr>
<tr>
<td>Formalized appeal process</td>
<td>for claimants</td>
</tr>
<tr>
<td>Prioritization</td>
<td>of timely resolution of claims</td>
</tr>
</tbody>
</table>

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.

QUEBEC VIC PROGRAM – 1988 to 2019

281 claims submitted

- 4 claims pending evaluation
- 195 claims with decisions
  - 44 claims not pursue
  - 80 appeals
    - 39 appeals rejected
    - 27 appeals withdrawn
    - 6 appeals accepted
  - 144 claims rejected
    - 27 appeals withdrawn
    - 6 appeals accepted
  - 51 claims compensated

$5.8 CAN millions

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

5.7 million Quebecers received the influenza A(H1N1) vaccine

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!