

Vaccine Injuries Compensation Programs in Different Countries: A Narrative Review

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INTRODUCTION

Vaccines have been used for hundreds of years to provide immunity to individuals thus expanding herd immunity and improving public health. Vaccinations can cause adverse effects such as anaphylaxis, brachial neuritis, vasovagal syncope, shoulder injuries, encephalopathies, arthritis, and death. In response to vaccine related injuries, deaths, ensuing litigation and the need to stabilize the vaccine market, Vaccine Injury Compensation Program (VICP) began to be developed. Germany was the first country to establish a VICP in 1961 and Iceland is the most recent in 2001. These programs were instituted as an alternative to the traditional civil law system for resolving claims. The VICPs were designed to be a no-fault claim system, providing indemnity to the pharmaceutical industry against adverse effects of mandatory or routinely recommended vaccines.

In May 1983, an international "Government Industry Liaison Panel" was established to guide legislators concerning vaccine injury. This panel included representatives from several organizations such as: The National Foundation for Infectious Diseases, Pan American Health Organization, the Centers for Disease Control, The Rockefeller Foundation and Wellcome Research Laboratories. When considering Vaccine Injury, the World Health Organization and most VICPs use the Bradford Hill Criteria, created in 1965 to link adverse events following immunization to the administration of a specific vaccine ¹.



OBJECTIVES

The overall objective of this review is to identify countries which have an operational vaccine compensation program. The specific objectives of this review are as following:
1. To identify vaccine related injuries (complications) and compensation programs worldwide
2. To identify specific vaccines that are covered under their respective compensation programs
3. To identify the funding sources and compare the level of compensation by different countries

RESULTS

Vaccine programs and vaccine initiatives worldwide are an unquestionable necessity for the continuance of mankind. However, in efforts to move forward with development of these programs, refusing to be bondage by oblivious ignorance of a vaccines possible negative outcomes, various governments have instituted programs to provide compensation to victims of vaccine injury. These programs have not been developed to promote the propagation of anti-vaccination but quite in contrast to advance the safe and confident government recommendation of usage of vaccines to the public. Our research has identified 16 countries in which the vaccine injury compensation programs (VICP) have unique qualities that are worthy of being emphasized. The following map identifies those evaluated 16 countries, on 7 continents including the year of their inception: Asia (Japan, Korea, Taiwan, Australia, Canada, US), South America, Antarctica, Europe (Denmark, Germany, Switzerland, United Kingdom, Finland, Norway, Sweden, France, Italy) and Australia (New Zealand). No vaccine injury compensation programs are located in Antarctica due to the absence of any permanent residents and all vaccine programs in Africa are administered through the Expanded Program on Immunization (EPI). An EPI does not yield any vaccine injury compensation program. No programs have been identified in South America.



Countries and provinces that have introduced vaccine-injury compensation schemes (including year of inception)

The unavoidable expansion of vaccine related injuries has been an understandable phenomenon when considering the amplification of the recommended childhood vaccine schedule over the previous 33 years. In 1986, 12 shots including 24 antigens and 8 diseases were recommended by the center for disease control for children worldwide. Over time, the vaccine injury risk has jumped to an astonishing level due to the incredible increase of the vaccinations recommended for children. Currently, in 2019 the center for disease control recommends 54 childhood vaccinations containing 70 antigens providing proposed protection against 16 diseases.



RESULTS

Country	Vaccine types	Compensable Vaccine Injuries	Pay-out in US dollars	Funding Source
Denmark	Polio, Measles, Diphtheria, Tetanus, Polio and Tuberculosis	Pain & Suffering Disability Death	\$100,000 (minimum \$60)	Central Taxation & Social Security
Germany	Mandatory and Recommended Vaccines	Medical malpractices Death, Severe Illness	No date available	General Revenue of the Länder (state governments)
Switzerland	Mandatory/Recommended All Licensed entering Switzerland to Wellcome	Medical malpractices All Licensed entering Switzerland to Wellcome	No date available	Cantons Federal Subsidies
UK	Recommended children vaccines, Adult influenza, Armed Forces vaccines	Severe disability	\$81.4 million (1976-2017) An average of \$2 Million per year	Public Funds National Treasury
Finland	Measles, Pain and Suffering Permanent Disability Cosmetic Injuries	Measles Death, Severe Illness Cosmetic Injuries	Annually 5992,000	Pharmaceutical Injury Insurance
Korea	DTaP, Tdap, Td, MMR, BCG, Japanese encephalitis vaccine, Rotavirus, Hepatitis B (not vaccine) (not MMR)	BCG lymphadenitis Stroke or other Severe Based on WHO causality assessment criteria	No date available	The Korea National Vaccine Injury Compensation Program (KVICP)
Hungary		51% injury caused by vaccine	\$1.1 Million less than 100 claims per year	Pharmaceutical Association
Sweden	MMN, HDV	Probable cause	\$105,000	Pharmaceutical Injury Insurance Government Insurance
China	MM, oral polio, Measles, MPRV	Death	\$10,400 average amount given out	Class 1 - Government Class 2 - Vaccine Manufacturer
Japan	Class 1:MMN, measles Class 2: Influenza	Medical, Natural, death Disability, Injury, Death	Top system for vaccine injury and vaccine maximum \$1 million	Class 1 - Health Service Bureau Class 2 - Pharmaceutical and Food Safety Bureau (PFSSB)
Taiwan	MMN, BCG, MMR	Death, serious Injury Permanent and Medical effects	\$200,000 Physical and mental damages \$100,000 - Serious Disease \$50,000 WHO Guidelines	Government programs, \$0.50 on each vaccine purchased Vaccine Injury Compensation Program
Canada	See list	Permanent impairment Incapacitation in Quebec	\$4.4 Million	Provincial Ministry of Health and Social Services
New Zealand		Permanent damage	\$2,800 average per claimant	General levy, investment returns
USA	Recommended Children Vaccines, Adult Influenza, Armed Forces vaccines	MMN (shingles), arthritis, stroke, and multiple sclerosis Autoimmune diseases Fetal paralysis plus Other vaccine injuries	No date available Death and actual and projected expense \$200,000	Vaccine excise tax
France	Mandatory Vaccines	Medical, disability, Social and medical	Data unavailable	National Treasury
Italy	Recommended Vaccines Diphtheria, Tetanus, Polio, Hep B, MMR, LMP, Rotavirus, Pertussis	Medical, Death Benefits Epilepsy, Chronic Fatigue Syndrome, Psychosis, Meningitis Thrombocytopenia, Transverse Myelitis	Data unavailable	Ministry of Health Government

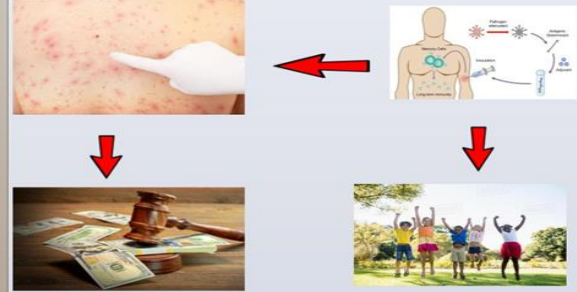
Compensation schemes are administrative system in all the countries except the USA. The United States VICP operates as a legal system and requires proof of causation based on epidemiological studies. The United States is the only country with a VICP program that involves the Justice department. The US program is jointly run by the Department of Health Human Services and the Department of Justice and Court System (6.5). Compensated injuries are those related to receiving government mandated, recommended, or WHO recommended vaccines. Studies show that compensation includes medical care, future care disability, funeral costs and death benefits for dependents or pain and suffering ¹⁶. Most countries require reporting of adverse events following immunization between 6 months and 3 years post injury ⁷.

In China, Switzerland, and Quebec (Canada), VICP is administered at the provincial level. Funding in China and Switzerland comes from the national government, while in Quebec (Canada) the only province with VICP is funded by the provincial government levy on vaccines. The Chinese and Japanese national governments have compensation for class 1 injuries, while class 2 injuries is covered by the vaccine manufacturers. Funding in European countries comes national government and Nordic countries such as Finland, Norway and Sweden from pharmaceutical injury insurance. The USA and Taiwan are considered standalones since their compensation programs are solely funded by vaccine taxation excise tax on vaccines ¹.

Conclusion & Future Research of Narrative Review

Vaccination Injury Compensation Programs are established on the principle of no fault claims, that is that the adverse effects are not related to an individual fault or a vaccine manufacturer but an inevitable consequences of medical intervention. The proof of causation differ among VICPs, hence there is no standard definition for a causation. Eligibility criteria for compensation is based on World Health Organization (WHO) list or the specific country's mandatory and routine vaccines. For example, in New Zealand, Finland, Denmark, Norway, and Sweden all vaccines are covered, while Japan, Italy, and Taiwan coverage is only provided for government recommended vaccines per the WHO vaccine table guidelines. The lowest vaccine injury payout was in New Zealand and the highest in Norway according to data results (table 1). The USA scheme is the most costly due to its legal based structure since claimants utilize legal representation when filing for claims. This has contributed to lengthy process contrary to the intended 240 days to resolve a case. As an alternative to the tort system, those who are dissatisfied with the decision of VICP could still seek compensation through civil court systems. The VICP initiative has stabilized the vaccine industry by ensuring an adequate supply of vaccines, managing the cost of vaccines, and has provided a means to compensate those who suffer adverse effects from vaccination. Compensation programs have restored population confidence in the safety of vaccination hence improving public health through provision of herd immunity.

Future research is needed to provide a more comprehensive data in respect to Hungary, Austria, and Slovenia all recognized by the WHO as having operating VICPs. Additional studies may provide exhaustive data on individual countries. Data concerning payout for each type of injury, number of claims, successful claims compared to rejected claims, and the most of least compensated injury related to a specific vaccine across all VICP would further validate our conclusions.



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