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Original Article

Updates on Vaccine Injury Compensation Program in Taiwan and Program Evaluation

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Abstract

In response to the outcome in which a child received oral poliovirus vaccine and subsequently developed polio in 1986 in Taoyuan area, the Department of Health implemented the Vaccine Injury Compensation Program (VICP) and established a Compensation Relief Funds that pays for vaccine-injured individuals in June, 1988 and held its first committee meeting in 1988. Later in 1992, Vaccine Injury Compensation Working Group was set up to conduct independent review of vaccine-related injury cases. The legislative objectives of the policy are to compensate vaccine-injured children and their family in a timely fashion, address public concern over vaccine safety, and simultaneously encourage parents to continue to have their children vaccinated, thus to maintain high vaccination coverage for certain vaccine-preventable diseases. This paper aims to give updates on VICP in Taiwan and further evaluates the Regulations Governing Collection and Review of Relief Fund for Victims of Immunization and proposes recommendations regarding future work.

Keywords: Vaccine injury compensation

Introduction

Immunization is considered to be one of the greatest successes in public health intervention in Taiwan. Through several immunization programs, Taiwan government had significantly reduced the HBV infection and carrier rate, achieved poliomyelitis eradication and lowered the incidence rate of vaccine-preventable diseases[1–2].

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However, while contributing to the protection of society from the threat of certain communicable diseases, few individuals will sustain rare and sometimes serious injuries as a consequence after vaccination. In response to the case in 1986, where a child received oral poliovirus vaccine and subsequently contracted polio, the former Department of Health, Executive Yuan, started the Vaccine Injury Compensation Program (VICP) by establishing Compensation Relief Funds and regulations in June of that year. A review group was also set up accordingly to adjudicate claims to address the public controversy over vaccine-related injuries that could possibly be attributed to the polio vaccine. The program's goals are to efficiently and effectively compensate vaccine-injured children and their family, and simultaneously encourage parents to continue to have their children vaccinated, thus maintaining overall vaccination coverage.

Materials and Methods

The statistics that are related to VICP are updated periodically by Taiwan Centers for Disease Control (CDC). These data can be directly accessed at the VICP section of Taiwan CDC website [3]. The statistics report detail the number of claims filed, number of claims reviewed and the number of claims compensated/dismissed and the amount of compensation awards by year. Moreover, the reports also detail the number of cases compensated by types of compensation and the number of settlement for claims compensated or dismissed by vaccine type. The statistics discussed in this paper include the number of claims filed and reviewed since program inception in 1986 until August 2014.

Legal Framework of Taiwan Vaccine Injury Compensation

The current legal framework for Taiwan Vaccine Injury Compensation Program is the "Disease Control Act" (Article 30) as well as the "Regulations Governing Collection and Review of Relief Fund for Victims of Immunization". These laws regulate administration, funding, eligibility, filing requirement, review committee, and types of compensation for the program. Moreover, these elements are similar to the ones identified by Clare Looker and Heath Kelly [4] and were used to introduce the vaccine injury compensation program in Taiwan.

- **Administration:** The VICP falls under the administration of Ministry of Health and Welfare, and the administrative affairs and preparatory work have been delegated to the Taiwan CDC [5].
- **Funding:** The Compensation Relief Fund provides funding for program to compensate vaccine-related injury. It is funded from the premium of NT1.5 dollars

imposed on each vaccine purchased by the government. The premium is paid by vaccine manufacturers or importers after purchased vaccines are approved and certified by Taiwan Food and Drug Administration (TFDA). However, the premium rate can be adjusted when the amount of the Fund either exceeds 2 hundred million or is less than 1.5 hundred million NT dollars [6] so that the Compensation Relief Fund is not over- or underfunded. Moreover, the Compensation Relief Fund is not restricted to compensation payouts only, it also provides funding for operating expenses and researches on adverse events following vaccination.

- **Eligibility:** The program covers all routine and compulsory vaccines that are approved and certified by the TFDA. It also covers emergency imported vaccines which will be used to halt outbreaks before they are permitted to be used [6].
- **Filing Requirement:** In order to qualify for compensation, the claimant must file the claim within 5 years after the onset of the adverse event or within 2 years of knowledge of the facts that the onset of the adverse event is thought to arise from vaccination [5].
- **Review Committee:** VICP Working Group (VICPWG) is set up by the former Department of Health (now known as Ministry of Health and Welfare) and authorized for reviewing vaccine-injury cases. The VICPWG consists of 19 to 25 members including experts in medicine and pharmacy, health, anatomy and pathology, law, and impartial members of the community, etc. However, legal experts or impartial members of the community (non-medical experts) must take up more than 1/3 of total members to oversee the functioning of VICPWG and medical review of each case [6].
- **Process:** The filing process is quite simple and straightforward. Any injured adult who has reached the age of 20 years old, or a legal guardian of injured child, or an heir at law of a deceased can file a claim. The claimant is required to fill out a claim form and describe adverse events following vaccination, and file the claim at local health bureau. After receiving a claim, the local health bureau will collect a set of medical records dated at least 1 year before and after the injury, and fill out an injury investigation form then send them to Institute for Biotechnology and Medicine Industry, which is entrusted with the management of preparatory work for claims review meeting, for further processing. Claims are first reviewed by two members carefully chosen from VICPWG based on their expertise and types of adverse events. The experts are responsible for reviewing medical records and determining whether the vaccine caused the injury using following criteria: (1) Is there any scientific evidence or medical research indicating that there is a relationship between the claimed adverse event and the particular vaccine; (2) Is there a logical chronological

order showing that the particular vaccine caused the adverse event; (3) Does the injured person have any health problem that could have been a cause for the injury. After reviewing the case thoroughly, the experts produce a review report and decided amount of compensation awards if applicable. Once the experts have finished reviewing the documents, the cases are brought to the VICPWG review meeting regularly arranged by Taiwan CDC. The meeting is held every other month, with a maximum interval of sixty days between two meetings, so as to ensure that the injury cases are solved in a timely fashion. A copy of summaries of medical records of the injured individuals are delivered to every VICPWG members 7 days prior to the review meeting, allowing them to thoroughly study the document. During the meeting, the chairperson moderates discussions and determines if there is a relationship between the adverse event and the particular vaccine and amount of compensation award. After a decision is made, the claimant is informed of whether or not the case is compensable.

- **Types of Compensation:** If a claim is decided as compensable, the amount of compensation award is determined by the level of casual relationship between adverse events and the vaccine as well as the severity of the injuries. The level of casual relationship is categorized into 3 types: related, possibly related, and unrelated. This allows the program to offer a more relaxed standard of proof and the benefit of doubt is resolved in the claimants' favor. On the other hand, the types of compensation are categorized as follows: compensation for death, compensation for impairments, compensation for severe illness, and compensation for other adverse events. If a claimant wishes to acquire compensation for impairments, the claimant must first obtain a disability identification card stating the type of disability that could have been caused by vaccination before filing a claim. Once causation is determined, the compensation can be granted for such disability. If the injury claimed meets the definition of severe illness regulated by the National Health Insurance Administration, the claimant can be entitled to compensation for severe illness once there is a casual relationship between the injury and the vaccine. In addition, a funeral subsidy can be given if an autopsy is performed to determine that the death is indeed caused by a particular vaccine. Moreover, a medical treatment subsidy can be provided to the injured person if the person has undergone necessary medical procedures to help clarify the causal relationship between the adverse event and a particular vaccine [6]. In summary, types of compensation awards and maximum amount payable are shown in the following table:

Table 1. Types of Compensation and Maximum Amount Payable

Types of Compensation	Definition / Level of Severity		Level of Casual Relationship	Max Payment (NTD10,000x)
Deaths			Related	50–600
			Possibly Related	30–350
Impairments	The injury falls within the scope of conditions covered by Laws for the Protection of the Rights of the Mentally and Physically Impaired	4-extremely severe	Related	50–600
			Possibly Related	30–350
		3-severe	Related	30–500
			Possibly Related	20–300
		2-moderate	Related	20–400
			Possibly Related	10–250
		1-mild	Related	10–250
			Possibly Related	5–200
Severe Illness	The sustained injury is listed in the list of severe illness maintained by National Health Insurance Administration.		Related	2–300
			Possibly Related	2–120
Other adverse reactions	Other adverse reactions that are covered by any specific policy		Related	0–20
			Possibly Related	
Funeral Subsidy	Autopsy			30
Medical Subsidy	Imposed to determine the link between the case and the vaccine			20
Fetal/Embryo Examination Subsidy				5–10

- **Litigation rights:** If the claimant does not accept the decision, or is not satisfied with the amount of the award compensated, the claimant has the right to file an appeal within 30 days after receiving decision with the Petitions and Appeals Committee, which is an agency responsible for adjudicating appeals of decisions made by the government. If the claimant still does not accept the decision rendered by the Petitions and Appeals Committee, the claimant can file a lawsuit against the Ministry of Health and Welfare.

  The Petitions and Appeals Committee so far has not overthrown a decision regarding the causation of injury made by VICPWG; however, there was a successful appeal against the decision in which the injured person was not compensated despite the fact that the injury was caused by immunization. Although the injury was relatively mild, the Petitions and Appeals Committee overruled this decision because the regulation did not specify under what circumstances the claimant is not entitled

with compensation when there is a casual relationship between an injury and immunization. Finally, this case was brought back to review meeting again and was granted reimbursement for medical costs. It also prompted the Taiwan CDC to propose further amendments to the Regulations Governing Collection and Review of Relief Fund for Victims of Immunization in 2013.

Results

- Until August 2014, a total of 1,399 claims were reviewed and 560 claims had been determined as compensable. The number of settlement for each year is shown in Figure 1. Moreover, 223 out of 839 dismissed claims, though not compensable, were given subsidies to cover funeral costs, medical expenses and fetal/embryo examination fee. The compensation awards and subsidies for claimants were paid from the Compensation Relief Funds and the amount had reached 95,599,487 NT dollars [3] . The payout for each year is shown in Figure 2. Moreover, the program is able to resolve injury claims in a timely fashion. In the year 2013, 98 injuries cases were resolved with an average processing time of 155 days from the date of acceptance.

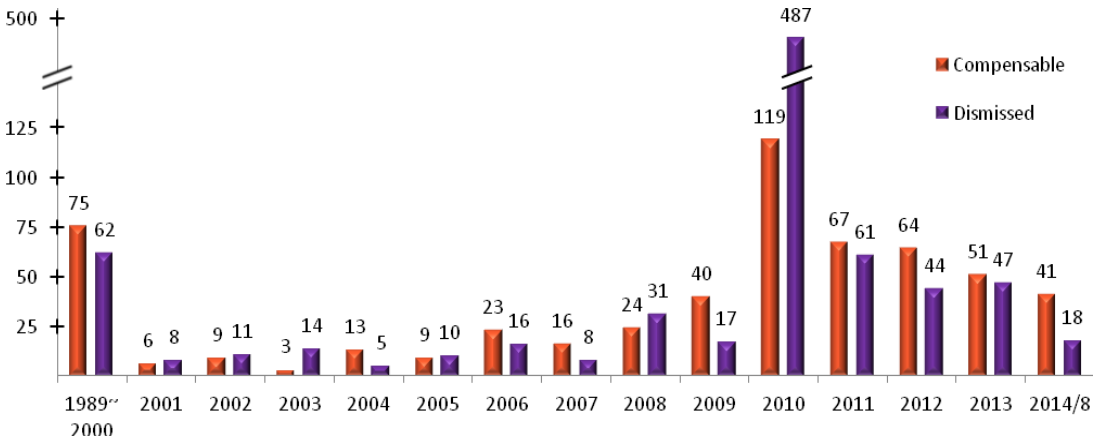

Figure 1. Number of claims compensated/dismissed for each year since program inception

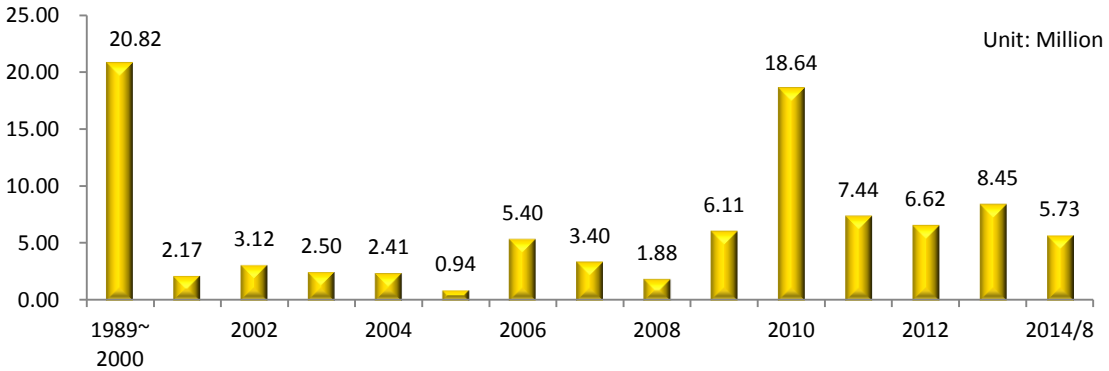

Figure 2. Program payouts for each year since program inception

- The most compensated vaccine-related claim is the BCG vaccine (156 out of 167 were compensated) because of the advent of techniques of BCG strain differential diagnosis and the implementation of active surveillance by Taiwan CDC on BCG related adverse events [7].
- The most recent controversy in VICP involves the large number of claimants who assert that there is a casual relationship between the influenza A(H1N1) vaccine and bell's palsy and the event concerning the death of a doctor's son after receiving A(H1N1) flu vaccination. The public concern over vaccine safety was all over the mass media, creating considerable anxiety in Taiwan and had led approximately 600 injury claims filed in VICP. After the year of 2010, VICP had approximately 50% of increase in the number of claims filed, compared to the number of claims in the year of 2008, as shown in Figure 3. The public awareness over the issue of vaccine safety and the existence of the vaccine injury compensation program was gained largely through the influence of mass media.

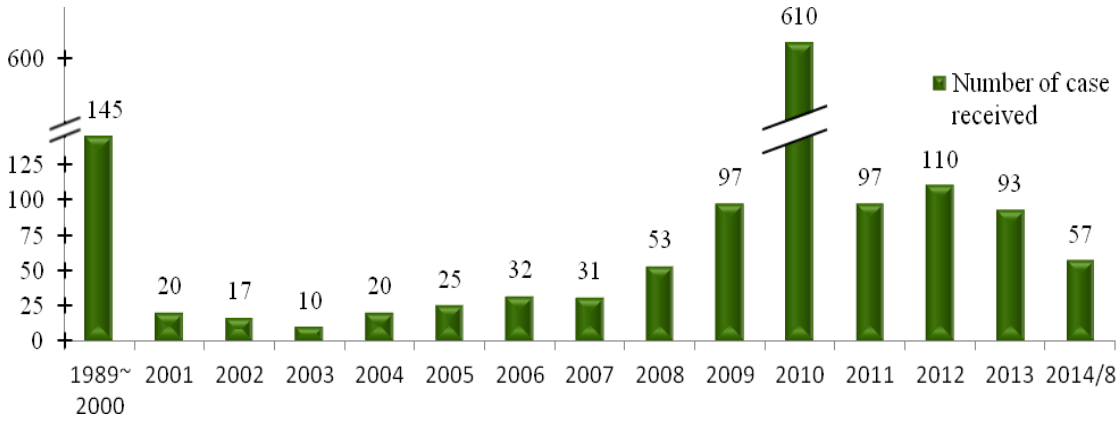

Figure 3. Number of claims received for each year since program inception

Recent Improvements on The Regulations Governing Collection and Review of Relief Fund for Victims of Immunization

In 2013, Taiwan CDC proposed a few changes to The Regulations Governing Collection and Review of Relief Fund for Victims of Immunization in order to improve some aspects of the program. Firstly, the program now covers emergency imported vaccines which will be used for vaccination to halt outbreaks before the vaccine are approved and certified by TFDA. Secondly, caps on some type of compensations are drastically raised in order to better reflect the impacts from vaccine-related injury on the family and the life of the injured person. Finally, the regulation was amended to state conditions for not providing compensation where ineligible claims are rejected before being forwarded to VICPWG for further review to help ensure effective use of compensation resources [6].

Evaluation of Vaccine Injury Compensation Program in Taiwan and Recommendations

VICP in Taiwan is generally successful. It is designed to provide compensation for people who may have been injured by immunization and settle injury claims in a timely fashion. It also helps maintain public confidence in the national immunization program. VICP puts no burden of proof on the claimant. All medical records are collected by local health bureau and sent to the VICPWG, which is responsible for adjudicating claims, has developed an internal consensus when reviewing injury claims. Decisions made among members are consistent both in types and amount of compensation awards. The committee membership also includes legal experts or impartial members of the community (non-medical experts) to oversee the functioning of the committee.

After reviewing the current scheme for vaccine compensation program in Taiwan, recommendations are proposed for future work regarding definitive restrictions on the filing requirement, and continuous attentions for the establishment of compensation principles and standards assessment.

Firstly, the filing requirement is too generous. The program only places restrictions on statute of limitations but not types or severity of injury that is eligible for claim. Therefore, the program allows claims for any outcomes following immunization. This has led some irrational individuals to file cases that obviously are ineligible for compensation. For example, a citizen filed a claim because he still contracted tetanus after receiving tetanus immunization. Such case can cause extra administrative overhead in the program. In 2013, Taiwan CDC amended the regulation to include conditions under which the claimant is not eligible to receive compensation awards; however, some of the terms used to describe the conditions, for example, “Commonly seen, mild, or expectable adverse reactions”, are still vague in definition. The ideal filing requirement would be to place restrictions on severity of injury for compensation by stating that the immunization must have caused bodily injury and the injury must exceed minor inconvenience of common adverse event, such as rash, swelling and redness around injection site, sore arm, fatigue, etc. As such, the injury cases that are ineligible for compensation are barred at the stage of application.

Finally, continuous attention for the establishment of compensation principles and standard assessment is required. Current determination for the amount of compensation awards uses the criteria specified in the Regulations Governing Collection and Review of Relief Fund for Victims of Immunization. However, the regulation only specifies types of compensation and maximum amount payable for injury claim with different level of severity and casual association between the injury and a particular vaccine. Moreover, the caps on some types of compensation are so high that it sometimes creates a false expectation and it usually turns out to be an unsatisfied result for the claimants.

Some claimants with serious injuries often argued the awards are too low to fully compensate for the losses sustained by the victim and the families. Therefore, a recommendation would be to include a protocol (perhaps something similar to standard assessment utilized by insurance company but a more liberal one) that calculates the monetary supports needed for severely vaccine-injured individuals. This would allow the VICPWG to take into full consideration the impact brought by vaccine-related injury and how it influences a person's life and his family, making the program more convincing in fulfilling its original legislative objective to provide just compensation for vaccine-injured individuals.

Conclusion

Vaccine-related injuries are unpredictable and unavoidable. In order to fully recognize the fact that people suffer from vaccine-related injuries because of their compliance to national immunization program, the government established the VICP. The program meets the original legislative objectives by providing compensation for individuals who may have been injured by immunization. The compensation includes different subsidies, and focuses on providing monetary for the injuries and their families. Individuals with vaccine-related injury who are entitled to compensation for Severe Illness or Impairments are furthered referred to social welfare agencies for follow-up assistance. However, the program should place definitive restrictions on the filing requirement to reduce administrative overheads and require continuous attentions for the establishment of compensation principles and standards assessment to make the program decisions more convincing in fulfilling its original legislative objective.

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