

Original Article

Comparison Analysis of Taiwan/Japan Vaccine Injury Compensation Program

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Abstract

As of 1988, Taiwan has established a vaccine injury compensation program; whether it is public or at self expense, as long as the procedures of qualification are met and certified, all are incorporated into our country's vaccine injury compensation program. The jurisdiction mainly belongs to DOH who then authorizes the Vaccine Injury Compensation Program Working Group and Centers for Disease Control for execution; the expenses are at the vaccine manufacturers' cost. In Japan, this system was established in 1976; the difference lies in the different jurisdictions of public-funded vaccines and self-paid vaccines, where the jurisdictions are held by Health Service Bureau and Pharmaceutical and Food Safety Bureau of Ministry of Health, Labour, and Welfare. The expenses however, also differ with the government budget covering those public-funded vaccine cases; on the other hand, the expenses for self-paid vaccine cases are covered by vaccine manufacturers, with additional fines added according to the degree of severity in each case. Due to the differences in the effectiveness of public health for public-funded and self-paid vaccines, how Japan adjusts the body held responsible and the amount of payments accordingly, and the structural concepts and execution experiences of incorporating self-paid vaccine into general drug side-effects mechanism is worthy of consideration and reference for our country.

Keywords: vaccine injury compensation program, Japan vaccine policy

Introduction

In Japan, the vaccine injury relief system was established in 1976. According to the different nature of public-funded and self-paid vaccines, different expense sources, review procedures, and handling units were distinguished. Due to the fact that our nation's vaccine injury compensation program is undergoing amending of income levy and review systems, the operating staff for the vaccine injury compensation program of the Centers for Disease Control (CDC) traveled to Japan in November of 2011 to the Ministry of Health, Labour, and Welfare

(MHLW), Pharmaceuticals and Medical Devices Agency (PMDA), and National Institute of Infectious Diseases to visit and share related experiences. Through this interview and discussion, we were able to further understand the structure of Japan's vaccine injury relief system which aids in providing references for future planning for related operations in our country.

Origin and Purpose for Taiwan's Vaccine Injury Compensation

In correlation with the incident in 1986 of oral vaccines for polio which caused a polio case, the Department of Health (DOH) invited representatives from the pharmaceuticals, law, and unions to study and refer to Europe, America, and other developed countries' system; and in June of 1988, the vaccine injury compensation fund was established. In 1992, the "Vaccine Injury Compensation Program Working Group (VICPWG)" of DOH was set up and authorized in independent reviews. It was hoped that through this compensation mechanism, if any of the public received vaccination that further caused death, physical and mental impairments, serious illness, and adverse reactions can receive reasonable compensation quickly after professional review to eliminate the possible doubts the public has for possible side-effects of vaccines, and elevate the vaccination rate. Costs associated with the compensation efforts, vaccine manufacturers are subject to statutory levy money when the vaccines are certified, and are managed and used in the vaccine injury compensation fund.

Taiwan's Vaccine Injury Compensation Program Working Group

Due to the fact that vaccine injury compensation involves the rights of the public, related review procedures are extremely cautious. Members of our VICPWG are made up of 19 to 25 infection specialists, neurologists, immunologists, pathologists, health care experts, legal experts, and social justice experts; among these, legal and social justice experts take up approximately one-third of the members, who cautiously, expertly, and justly discuss matters. The VICPWG will make a decision only after reviewing the situations provided by the case applicant, referring to the medical records, test results, medical treatment received, the course of the disease, and vaccine traits and referring the academic studies, reports, and clinical data in discovering the possible relations between the injury and vaccination.

The Operation Procedures and Situation of Taiwan's Vaccine Injury Compensation

After the establishment of this compensation system in Taiwan, whether it is public-funded or self-paid, both are under the same system with the same reviewing criteria; all the claims are received by jurisdictional health bureaus from public application, and after gaining access to medical records and preliminary investigation, the claims are sent to CDC of DOH for further inspection and compilation. After the preparation of related information, they are then sent to the VICPWG for further review. After administrative sanctions are achieved according to the decision the panel makes, the notification of results and request for payment

are conducted. Part of the administrative general affairs and preparatory work for this operation, as of 2008, has been entrusted to the Taiwan Drug Relief Foundation (TDRF). Currently, the procedure for Taiwan’s vaccine injury compensation review is shown in Figure 1.

Looking at the compensation articles and payment standards, including death payment, payment for physical and mental impairments, serious illness payment, and adverse reaction payments, according to the relativity to the vaccine and severity of the disease, the highest payment amount are 6 million, 5 million, 1 million, and 200 thousand New Taiwan Dollars (NTD). If an autopsy or reasonable tests were conducted, in order to determine the incident’s relation to a vaccine, reasonable subsidy can be authorized for funeral, medical, pregnancy fetal tests, or infant autopsy fees. Until 2011, the review and compensation situation for vaccine injury compensation claims in the previous years can be seen in Figure 2.

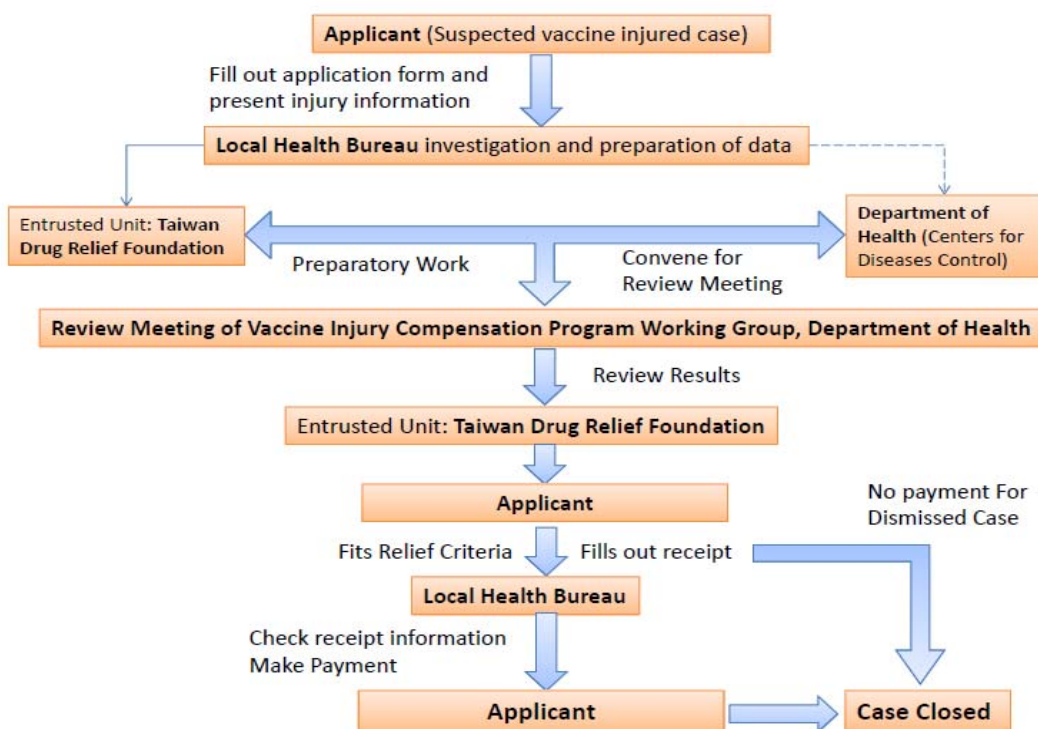


Figure 1. Taiwan Vaccine Injury Compensation Review Procedure

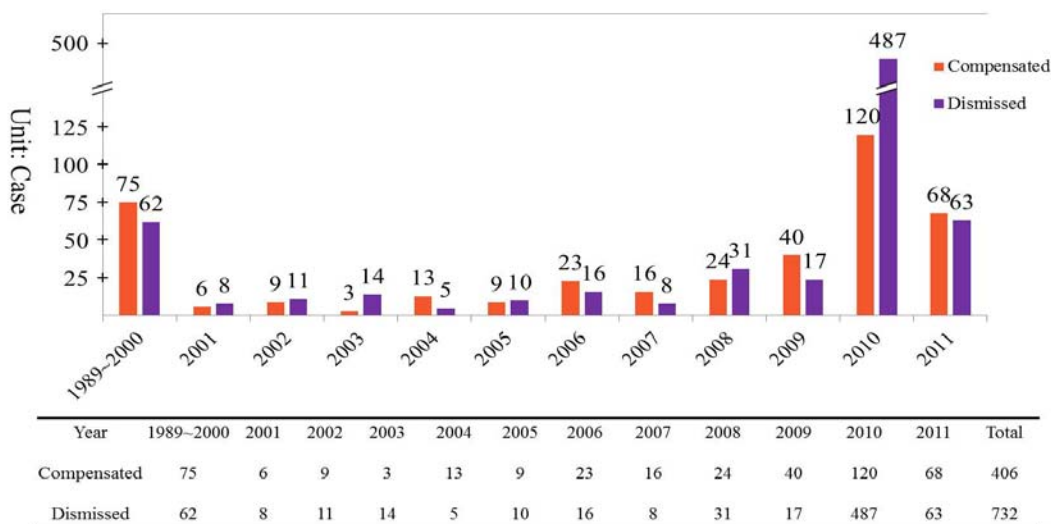


Figure 2. Taiwan Review and Compensation Situation for Vaccine Injury Compensation Claims in Recent Years

Introduction to Japan's Vaccine Policy

In Japan, the vaccine policy and jurisdiction, according to public-funded and self-paid markets, they are governed by the Law for Immunization and the Pharmaceutical Affairs Law respectively. The Law for Immunization was promulgated in 1948, in order to reform the infectious disease epidemic after the World War II; to set up the vaccination policy and to compel the public by law to receive vaccination, if not, punishment was administered. Afterwards, public opinion gradually started to acknowledge and emphasize the importance of the medical care system and agree to different types of injury relief mechanisms, in 1994, an amendment was issued in which the government no longer compels the public to receive vaccine but “encourages (persuades)” vaccination. In 2001, public-funded vaccines were separated into routine vaccines and non-routine vaccines; among which routine vaccines are classified into Class I and Class II; the Class I is encouraged (persuaded) to be vaccinated whereas the Class II is only advised. The classes and types of vaccinations can be seen in Figure 3 [1-2].

In Japan's vaccine policy decision-making system, the Health Service Bureau (HSB) of MHLW and its committee are responsible for “the Law for Immunization” and the establishment of vaccine policies. As for the approval of vaccines, manufacturing, testing and certifying, and safety monitoring, these are under the jurisdiction of Pharmaceutical and Food Safety Bureau (PFSB) of MHLW. In addition, the National Institute of Infectious Diseases is responsible for providing related scientific statistics for epidemiological surveillance research and policy decisions. In the future, it is planned to merge the related vaccine units under the HSB and PFSB and establish a vaccine policy office under Tuberculosis and Infectious Diseases Control Division (TIDCD) of the HSB.

Looking at the financial resource of public-funded vaccines, principally, apart from those low-income families where subsidies are provided by the central government, all other routine vaccines are provided by local municipal governments. As for non-routine vaccines during epidemic seasons, they are provided for by municipal or prefectural governments. When

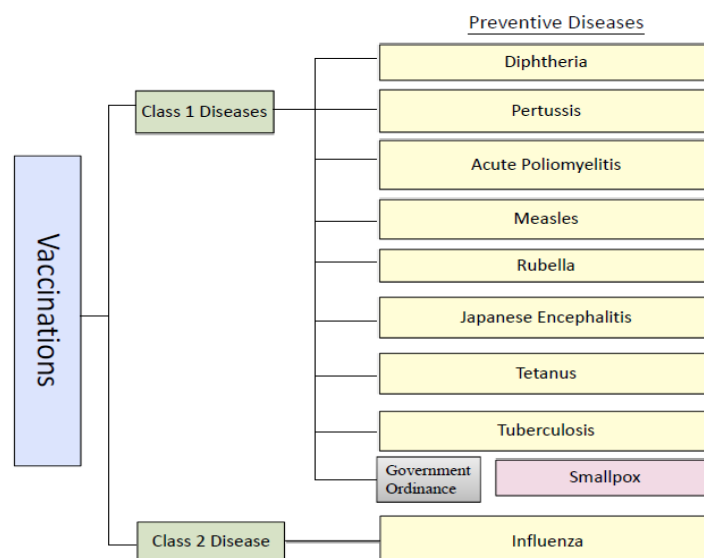


Figure 3. Japan's Public-Funded Vaccine Classes and Types

a person brings his/her child with a government-granted vaccine note to hospitals to receive testing and vaccination, afterwards, they can apply for the cost of the vaccination with the local government.

According to the decision made by Vaccination Panel Meeting in October of 2010, in consideration of international trend and the severity of the disease, it is planned to make amends to the Law for Immunization; of which, the human papilloma virus vaccine, haemophilus influenza type b vaccine, pediatric pneumococcal vaccine are to be incorporated into routine vaccines. This is temporarily set to operate in 2012 or 2013.

The Evolution of Japan's Vaccine Injury Relief

Earlier, after the World War II, the Japanese government preventive policy focused on reducing the number of infectious disease cases, even fining those who did not receive vaccination as regulated. At the time, the side-effects of vaccinations were only potential cases, where they were thought of as a result of individual physical fitness. After 1965, due to the increase in persons who showed health problems after vaccination, related petition and litigation cases started to shape a social issue. This leads to the first amendment of the Law for Immunization in 1976, which added Japan's vaccine injury relief system. However, the side-effects of vaccines were still regarded as inevitable incidents. After 1985, the side-effects of vaccinations were believed to be avoided, the government's role started to change from an infectious disease control point of view to ensuring the safety of vaccines. Looking at the vaccine injury relief system, whether it is public-funded or self-paid, if a vaccine is approved for the market, although the application, review laws, responsible units, and procedures differ, all have protection mechanisms and channels. The comparison Taiwan's and Japan's background in handling units and review procedures for public-funded and self-paid vaccine, along with the claimants for relief payment, application time frame, and application documents required can be seen in Table 1 and 2 [2-3].

Table 1. Taiwan and Japan Comparison of Backgrounds for Vaccine Injury Relief

Vaccine Type	Applicable Law	Handling Unit	Beginning Date/Payment Source	Review Results Approval Unit
Taiwan Tested Approved Certified Vaccine	Communicable Disease Control Act, Regulations Governing Collection and Review of Relief Fund for Victims of Immunization	Local health bureaus, CDC of DOH (Entrust to TDRF)	1988 Levy is collected according to levy laws from vaccine manufacturers. (current standard is 1 NTD for each dosage)	VICPWP of DOH
Japan Public-funded vaccine	The Law for Immunization	Local health bureaus, TIDCD of HSB, MHLW	1976 Central government budget (MHLW): 1/2 Local government budget (prefectural or municipal government) : 1/2	Disease and Disability Certification Council (DDCC) of HSB
Japan Self-paid Vaccine	Incorporated Administrative Pharmaceuticals and Medical Devices Agency Law, the Pharmaceutical Affairs Law	PMDA (authorized units by PFSB of MHLW)	May 1, 1980 Relief expenses: Additional levy collected from vaccine manufacturers according to sales volume and actual relief situation. Administrative expenses: Central government (MHLW) covers 1/2.	Pharmaceutical Affairs and Food Sanitation Council (PAFSC) of PFSB

If side-effects are shown after vaccination, in payment types and amount, it can be categorized into two different amounts. Among these, since Class I vaccines and non-routine vaccines are persuaded (encouraged) by the government for inoculation, the Japanese government believes that the public receives injury after receiving a government policy-encouraged vaccine; the payment should exceed other cases. The comparison between the different vaccines and Taiwan's payment types and amount can be shown in Table 3 [2].

In the statistics of application and review results, as of 2007, Japan has received approximately 70 vaccine injury relief cases each year for public-funded vaccinations, with a payment rate that reaches about 80%. By analyzing the different types of payment, 80 percent are issued for healthcare benefits or medical allowance. As for disability annuities and funeral fees, the cases number is no more than 10. In addition, the vaccine injury relief system in Japan, starting from the date of its operation to 2010, a total of 2,751 cases were paid for; among these, the most cases were for the measles, mumps, and rubella (MMR) vaccine, taking up more than

Table 2. Taiwan and Japan Comparison of Related Application Regulations for Vaccine Injury Relief

Nationality	Payment Types	Claimant	Claim Time Frame	Needed Documents	
				Application Form	Attachments
Taiwan	Not differentiated (decided by VICPWG)	Victim Guardian (underage cases) Heir (death cases)	Within 2 years of knowledge; within 5 years of date of incident	Application form	Photo, diagnosis certificate (not mandatory)
Japan	Healthcare benefits	Victim	Within 5 years from date of first medical assistance	Healthcare benefits, medical subsidy request	Healthcare benefits, medical subsidy request, prescription certificate or receipt, checkup certificate, other
	Medical allowances		Within 5 years from 1 st day of following month after medical assistance		
	Disability Childcare Pension	Guardian	No limit	Pension for families raising children with disabilities request	Disability pension, Pension for families raising children with disabilities request Prescription and usage certificate or receipt Other
	Disability pension	Victim	No limit	Disability pension request	
	Bereaved family Pension	Heir	Within 5 years after death	Bereaved family 's pension request	Bereaved family pension, Bereaved family sum, funeral material certificate Prescription and usage certificate or receipt Other
	Lump-sum benefit for bereaved family	Heir	Within 5 years after death	Bereaved family sum request	
	Funeral assistance	Heir	Within 5 years after death	Funeral material request	

Table 3. Taiwan and Japan Comparison of Various Vaccine Relief Types and Payment Amount

Taiwan		Japan				
Payment Types	Various Vaccines	Payment Types	Public-Funded Vaccines Class I vaccines, non-routine (emergency) vaccines	Public-Funded Vaccines H1N1 influenza vaccine	Public-Funded Vaccines Class II vaccines	Self-Paid Market Any type of vaccine
	Tested, approved, and certified by DOH		Vaccines for diphtheria, pertussis, oral polio, measles, rubella, Japanese encephalitis, tetanus, BCG, smallpox	H1N1 influenza vaccine	Elderly influenza vaccine	Vaccines such as Hib, streptococcus pneumoniae, influenza, chicken pox, hepatitis B, hepatitis A, HPV, etc.
Medical subsidy	Highest 100 thousand NTD	Healthcare benefits	Self-payment amount excluding the benefit covered by health insurance			
Payment for adverse reactions	Highest 200 thousand NTD	Medical allowance	Not hospitalized under 3 days		33,800 Yen/month	
Payment for serious illness	Highest 1 million NTD		Not hospitalized over 3 days		35,800 Yen/month	
			Hospitalized under 8 days		33,800 Yen/month	
			Hospitalized over 8 days		35,800 Yen/month	
			Both hospitalized and not hospitalized 35,800 Yen/month			
Payment for physical and mental impairments	Highest 5 million NTD	Pension for families raising children with disabilities	Level 1 1,531,200 Yen/year Level 2 1,225,200 Yen/year	Level 1 850,800 Yen/year Level 2 680,400 Yen/year	None	None
		Disability Pension	Level 1 4,897,200 Yen/year Level 2 3,915,600 Yen/year Level 3 2,937,600 Yen/year	Level 1 2,720,400 Yen/year Level 2 2,715,600 Yen/year		
		Supplementary nursing care benefits	Level 1 839,500 Yen/year Level 2 559,700 Yen/year	None	None	None
Death payment	Highest 6 million NTD	Bereaved family Condolence Fee	None	7,135,200 Yen		
		Bereaved family Pension	None	Highest for 10 years 2,378,400 Yen/year		
		Lump-sum death benefit	42,800,000 Yen	None	None	None
Funeral assistance	Set at 300 thousand NTD	Funeral assistance	201,000 Yen			
Subsidy for embryo tests or fetus autopsy	100 thousand or 50 thousand according to pregnancy					

Note: 1 NTD is approximately 2.75 Yen

1/3 of all cases. Following are for the BCG vaccine where more than 460 cases were paid for. In self-paid vaccine cases, according to PMDA, the numbers resulting of side-effects injury relief show an increase in applied cases each year. From 2005 to 2008, a total of 124 side-effect cases were paid for, with 50% for seasonal influenza vaccines and 42% for mumps vaccines.

Relief Process for Japan's Public-funded Vaccine Injuries

Japan's municipal governments not only administer vaccinations and receive injury relief applications but also set related operation guidelines or handling procedures. According to the 11th article in the Law for Immunization, after a person receives vaccination, if suspected disease, disability, death, or adverse reactions occur, whether it is caused by the side effects of the vaccine or due to negligence during the vaccination process, he/she can file a claim at the municipal health section. The "Vaccine Health Injury Investigation Committee" of the municipal government will then conduct investigation of the case and preliminary review. Afterwards, the case files and investigation report is sent to the TIDCD of HSB, MHLW through the prefectural government; where DDCC will make the final decision and MHLW will notify the applicant the results of the application through the prefectural and municipal government.

According to the 12th article of the Law for Immunization, whenever a case is determined by DDCC to be related to the vaccine and according to the severity of the situation, set a type of relief for the case, including healthcare benefits, medical allowance, pension for families raising children with disabilities, disability pension, supplementary nursing care benefits, lump-sum benefit for bereaved family, bereaved family pension, lump-sum death benefit, and funeral assistance. The definitions for these articles are listed in Table 4 [2]. As for the payment amount, it can be categorized into two types, set amount and yearly amounts. According to the level of vaccine listed in the Law for Immunization, different amounts are set. As for public-funded vaccine relief payments, the national budget covers them with MHLW sharing 1/2, prefectural government sharing 1/4, and municipal government sharing 1/4.

Table 4. Definitions of Japan's Vaccine Injury Relief Payment

Type of Payment	Definition
Healthcare benefits	Self-payment amount excluding the benefit covered by health insurance
Medical allowance	Inpatient/outpatient medical expense (paid on monthly basis)
Pension for families raising children with disabilities	Those age under 18 and fit level 1 and 2 disability appraisal
Disability pension	Those age above 18 and fit level 1-3 disability appraisal
Supplementary nursing care benefits	Cases of disabled which fit level 1 or 2 and need house nursing
Lump-sum benefit for bereaved family	Death victim (not primary source of family income)
Bereaved family pension	Death victim (primary source of family income)
Lump-sum death benefit	Provided for victim's family
Funeral assistance	Payment for the funeral service

Relief Process for Japan's Self-Paid Vaccine Injuries

After receiving vaccination of self-paid vaccines approved of by The Pharmaceutical Affairs Law, the injury relief application and review process are regulated by the pharmaceutical side-effect injury relief system of the “Incorporated Administrative Pharmaceuticals and Medical Devices Agency Law” and the related articles in “The Pharmaceutical Affairs Law”. If any person shows suspected disease, disability, death, or any other adverse reaction after vaccination, apart from situations where medical negligence was present in the vaccination process where no relief is provided, he/she may apply for review of all types of payment article by showing related documents to the Office of Relief Fund, PMDA. These are then sent to PFSB of MHLW, where PAFSC will make the final decision. Afterwards, the PMDA will notify the applicant on the results of the application; then he/she may apply for relief payment from the PMDA.

As for the budget source for the PMDA self-paid vaccine injury relief, the relief payment is levied from the vaccine manufacturer according to their sales volume using a set rate (the current set rate is 0.35% of their sales volume), and a 1/4 of the actual relief amount is also levied. As for the PMDA administrative fees, PAFSC of MHLW will cover 1/2 of the cost [3].

Discussion

Following are comparisons and discussions of Japan's and Taiwan's vaccine injury relief system, operation experience of review mechanism and review standards. For public-funded vaccines in Taiwan and Japan, the operating mechanism can be seen in Table 5. We hope this can be used for future system review and research reference in Taiwan.

Table 5. Comparison of Taiwan and Japan's Public-Funded Vaccine Injury Relief Operation Mechanism

Article	Taiwan	Japan
Beginning Year	1988	1976
Scope	Tested, approved, and certified vaccines	Announced public-funded vaccines; Self-paid vaccines are incorporated into general drug injury relief mechanism
Legal basis	Communicable Disease Control Act, Regulations Governing Collection and Review of Relief Fund for Victims of Immunization	the Law for Immunization
Main jurisdiction	DOH (CDC)	MHLW
Review and judgment unit	VICPWG	DDCC
Review point	Decisions are made according to relativity and severity of adverse reaction (classified as related, possibly related, and unrelated), also decided are payment articles and amount.	Whether payment of the application will be made or according to relativity and severity of adverse reaction (set amount, with yearly pay).
Review process	Central review after being sent by local health units	Central review after being sent by local health units, local health units provide preliminary assessment
Payment source	Levy from manufacturer	National budget

1. Independent operations for public-funded and self-paid vaccine injury relief systems

Japan's self paid vaccine injury relief system belongs to the Pharmaceutical Affairs Law and is under the jurisdiction of PFSB of MHLW. The manufacturing, supply, safety monitoring after marketing and injury relief of the vaccines are regulated as would any other general drug with the vaccine manufacturer responsible for relief. Public-funded vaccines, on the other hand, are administered based on the Law of Immunization and under the jurisdiction of HSB of MHLW and the payment source is from the national budget. In accordance with the national vaccine policy for public-funded vaccine victims, the payment is much higher than victims of self-paid vaccine. Looking back at Taiwan's vaccine injury compensation program, there is no discrepancy between public-funded or self-paid vaccines; all are under the jurisdiction of CDC of DOH. However, there were no differences in terms of payment source and standards. Due to the differences in vaccine effectiveness of public health and level of scientific support, public-funded vaccines and self-paid vaccines have different vaccination traits and purposes. Therefore, the legal basis, jurisdiction, and policy of vaccine supply are classified into 2 systems in both Taiwan and Japan. Only Japan has continued the management perspective of 2 systems to set up different payment amounts and sources according to the responsibility for the injury. Along with the actual injury payment, the levy collected from the self-paid vaccine manufacturers is increased. In Taiwan's injury relief, vaccines are not differentiated and all are handled by CDC; in addition, the country does not need to cover the payment because the vaccine is public-funded or that the relief payment is smaller because the vaccine was self-paid for. To sum up, in vaccine injury relief systems, Japan's operation system seems to be more reasonable than Taiwan's current operation system.

2. Review mechanism

In Japan, before vaccine injury cases are sent to DDCC and PAFSC for review, relevant investigation and opinions have been completed. For example, in public-funded vaccine cases, the municipal government has an established specialized committee, formed by internal medical health officials and jurisdictional medical-related experts which make a preliminary judgment according to the situation for each case. As for self-paid vaccines, the preliminary report is provided to MHLW by a relevant committee under the PMDA. In other words, in the review of cases in Japan, whether it is for public-funded vaccines or self-paid vaccines, both are reviewed in two stages by corresponding committees. Looking at the situation in Taiwan, although the local government health bureaus receive vaccine injury applications and needs to fill in a investigation form which describes the adverse reactions shown after vaccination in each case, the content is often a simple investigation report made by the nurses at a

health bureau through accessing the National Immunization Information System (NIIS) and conducting home interview (or phone interview); the expertise of the aid of this investigative report to the central government review committee is lower than that of Japan's. In addition, although Taiwan also entrusts TDRF to conduct relief-relevant administrative operations, they are only responsible for handling administrative work and document organization. Compared with the investigation and preliminary review done by the PMDA, the independency and initiative of the unit entrusted in Taiwan seems to be not enough. To sum up, whether to take Japan's system into consideration and revise the review procedures and documents provided by local health bureaus and TDRF to elevate the quality of review documents, is an issue we discuss in the future.

3. Review Standards

Looking at review standards and the formation of decisions, Japan is generally the same as Taiwan, with a review committee which discusses and reached a mutual decision. However, the differences are, Japan has a set payment amount for different articles, and the review committee only need to determine whether the case has an undisputed correlation with the vaccine or not, and whether it fits the standards for payment or not. On the other hand, in Taiwan, the review decision and payment amount will differentiate in each case according to the high/low relations to the vaccine and severity. After free discussion done by review committee members, different payment results will appear and before the law and justice personnel make the final decision, they will submit public view opinions, and the payment amount of those cases which have similar medical situations but different social situations will be slightly altered. Summing up, although the current system and review decision in Taiwan has the characteristic of having diverse considerations, this also results in no related standards for the public and medical personnel to reference to for possible payment disease types and amount. In addition, in Taiwan's current laws, the review decision needs to determine the case as "related, possibly related, or unrelated," however, there is still partial uncertainty in medics and there is a 1% to 99% rate in "possibly related," which often leads to debate during reviews, which also leads to misunderstandings when people read the content of administrative sanctions. On the other hand, in Japan, the results have no "related, possibly related, or unrelated" decision and only the choice to sanction the relief payment or not.

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Outbreak Investigation Express

A Cluster of Enterovirus Infection with Severe Complications in Northern Region of Taiwan, August 2012

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Abstract

On August 6th, 2012, a three year-old boy was notified as a suspect case of enterovirus infection with severe complications (EVSC) by a medical center in the northern region of Taiwan. Unfortunately, this EVSC case died before dawn on August 5th, and followed by the notification of his twin brother as a suspect EVSC case on August 7th, 2012. These two suspect EVSC cases were confirmed as enterovirus 71 infection with severe complications. From the epidemiologic investigation, there were four contacts who were younger than five years old, and all of them fell ill and diagnosed as enterovirus infections. The objectives of this epidemiologic investigation were to elucidate the occurrence of enterovirus infection clustering at the epidemic scene (household) and to avoid the consecutive waves of EVSC clustering among the contacted children. Our prevention and control measures were performing health education on how to prevent enterovirus infection for family members of ill children, providing isolated medical care to symptomatic children, and making daily telephone health care follow-up and reporting back to the Second Branch of Taiwan Centers for Disease Control (TCDC) during onset period by the local health bureau. Moreover, both of the Second Branch at TCDC and the local health bureau held Case Conference on EVSC accordingly in order to improve the ability of health care workers in diagnosing and managing cases contracted enterovirus infection through case discussion and

experience sharing. Under the cooperative efforts of the health authorities and medical team, there was no any additional EVSC case since then.

Keywords : Enterovirus infection with severe complications (EVSC), clustering, enterovirus 71, hand-foot-mouth disease (HFMD)

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