A Comparative Analysis on the Vaccine Injury Compensation Programs in the United States of America, Taiwan, and the Republic of Korea.

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Abbreviations

AEFI	Adverse Events Following Immunization
CDC	Centers for Disease Control and Prevention
CFC	U.S. Court of Federal Claims
CICP	Countermeasures Injury Compensation Program
DTP	Diphtheria, Tetanus and Pertussis (vaccine)
FCC	The United States Federal Courts of Claims
HHS	U.S. Department of Health and Human Services
KACVIC	The Korea Advisory Committee on Vaccine Injury Compensation
NCIRD	National Center for Immunization and Respiratory Diseases
NVICP	National Vaccine Injury Compensation Program
VICP	Vaccine Injury Compensation Program
VICPWG	Vaccine Injury Compensation Program Working Group
VPD	Vaccine Preventable Diseases
WHO	World Health Organization

= ABSTRACT =

A Comparative Analysis on the Vaccine Injury Compensation Programs in the United States of America, Taiwan, and the Republic of Korea.

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Objectives: With the COVID-19 pandemic, vaccine safety is receiving more attention than ever before, as reports of suspected COVID-19 vaccine injury cases rise at an alarming rate. Vaccination safety thus became a societal problem, and as public concern about the vaccine grew, so did the demand for national vaccine safety management. As an alternative to encouraging vaccine manufacturers to invest in research and development of vaccines and to fostering a better environment for healthcare providers and the vaccinees, 25 WHO jurisdictions have established National Vaccine Injury Compensation Programs according to 2019 data. Compensation programs are quite complex in forms; therefore, comparative analysis of vaccine injury compensation programs in the United States of America, Taiwan, and the Republic of Korea will be analyzed for future policy recommendations.

Subjects and Methods: This research was conducted through a comparative method by analyzing published journal articles, news media, government publications, governmental and other official Youtube channels, government websites, published books, legislations regarding vaccine injury. Using the most similar systems design (MSSD), the articles and

documents were used to verify structural and legal similarities and different factors of VICPs in the United States of America, Taiwan, and the Republic of Korea.

Results: Findings show that the main differences of the three countries were in the administration and sources of funding. The United States of America and Taiwan both relied on vaccine levies from manufacturers whereas the Korean VICP relied mainly on the government treasuries. Additionally, Korean VICP has an eligibility requirement that limits individuals who spent less than 300,000 won on their injuries from filing compensation claims, which is indicative of the fact that Korean VICP is designed to compensate serious injuries caused by immunization. However, the difference in administration funding source sheds light on the lack of sustainability of the Korean government's VICP operational system.

Conclusion: To implement vaccination programs successfully, we must address the problem of vaccine safety and overcome it to provide herd immunity and protect the population from diseases. The difference in administration funding source sheds light on the lack of sustainability of the Korean government's VICP operational system. This study suggests that Korea should establish a special contingency fund that operates year-round, with comparison to CICP in the States. However, the compensation review process should be made more transparent to enhance public trust and increase vaccination rates in times of national crisis. Second, the Korean government should impose a levy on vaccine manufacturers like the United States and Taiwan to operate a sustainable program that does not burden the government budget in national emergencies.

Key words: Vaccine injury, Injury compensation, Vaccine safety, Vaccine law, Adverse Events After Immunization (AEFI)

1 Introduction

1.1 Background of the Study

1.1.1 COVID-19 Pandemic and the Importance of Vaccination

The COVID-19 pandemic has exposed humanity with its vulnerabilities to diseases by causing irreparable damages in all parts of our lives. The advent of this unknown virus rendered us devastated with its rapid transmissibility, infectivity, and unending mutations. It reminded us of the importance of development and production of vaccines, procurement of resources, nurturing health professionals, and strengthening health systems. But most importantly, we now understand the key to defeating the pandemic and to protecting the people is vaccination. Attaining immunity against the virus in population level will prevent the disease from spreading.

COVID-19 isn't the first pandemic that caused severe issues about our public health, and it won't be the last. Throughout the history, there were many diseases that swept across communities and beyond nations. There was the Black Death (bubonic plague) in 1350 which claimed the lives of one-third of the world's population (History.com Editors, 2019). Then there was the 1918 Spanish flu (H1N1 virus), which was thought to have affected one-third of the world's population (Centers for Disease Control and Prevention, 2019). The first flu vaccine was developed in 1942 using fertilized chicken eggs, a process that took more than 20 years to complete (Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 2019). In the United States alone, flu shots prevented estimated numbers of 7.5 million influenza infections and 3.7 million influenza-related hospitalizations, and 6,300 influenza-related deaths during 2019-2020 (Centers for Disease Control and Prevention, National Center for Immunization and

Respiratory Diseases, 2021). Before its eradication in 1980, smallpox claimed the lives of more than 300 million people within the 20th century (National Geographic, 2021). This eradication was exclusively due to successful vaccination campaigns, and it is regarded as one of the greatest triumphs in the history of immunization programs.

1.1.2 Vaccine Safety and Public Concern for Adverse Events

Unlike these success stories, there are challenges such as vaccine hesitancy and fear that need to be solved. Vaccine hesitancy, according to WHO, is defined as "delay in acceptance or refusal of vaccines despite availability of vaccine services (Butler, 2016)". Vaccine hesitancy is driven by vague fear, ineffective risk communication, biased media coverage of rare side effects, misinformation, and a combination of these factors present major challenges to public health (Lane et al., 2018).

One of the most known examples of anti-vaccination movement stemmed from claims alleging connection between autism and vaccinations. The results of a recent study by The National Academy of Medicine (Institute of Medicine of the National Academies, 2012), debunked controversies that vaccines cause autism, but many individuals still resist against vaccinations. Hence, more governmental efforts are needed to address vaccine hesitancy and to protect individuals from vaccine-preventable diseases. Efforts to extinguish fear and anxiety of the public would ultimately increase vaccine coverage rates (Butler, 2016).

Individuals are expected to participate in national immunization programs for the benefit of not just individuals but for the nation as well. However, most vaccines inevitably entail risks of adverse events. There are many known side effects of various types of vaccinations. Some are claimed to be associated with vaccines, others are officially recognized by medical institutions or governments. The adverse vaccine reactions,

though rare, can be anywhere from mild to severe hypersensitive allergic reactions to any of the ingredients of the vaccine. These side effects include mild symptoms like fever, vomiting, diarrhea to serious side effects like Guillain-Barre syndrome, anaphylaxis, brachial neuritis, encephalopathy, and skin rashes (Chung, 2014; Stratton, Howe and Johnston, 1994).

1.1.3 The Need for Liability for Adverse Events

With the COVID-19 pandemic, vaccine safety is receiving more attention than ever before, as reports of suspected COVID-19 vaccine injury cases rise at an alarming rate. As an alternative to encouraging vaccine manufacturers to invest in research and development of vaccines and to fostering a better environment for healthcare providers and the vaccinees, the Korean government established a National Vaccine Injury Compensation Program (hereinafter, NVICP). The creation of this program was a statement to ensure adequate amount of vaccine supplies, to provide social protection against any potential vaccine injuries, and ultimately to enhance vaccination rates of the public. This program is designed to address vaccine hesitancy and fear by guaranteeing compensations in cases of side effects.

Alleged victims of vaccine-related adverse events find it difficult to be financially compensated for their loss because in the process of vaccinations follows various stakeholders which includes pharmaceutical manufacturers, logisticians, medical practitioners and so on. In cases of alleged vaccine injury claims, it is seemed onerous for the claimant to prove which party is responsible for the injury. In addition, if manufacturers of vaccines, transporters and custodians of vaccines, and immunization practitioners such as doctors and nurses are subjected to excessive legal liability, such as product liability or negligence, manufacturers or operators are afraid of legal responsibility. By no longer

producing vaccines or refusing to administer vaccinations, there is a possibility that the health of the whole nation may be threatened in the end, and researchers will be neglected in the research and development of new vaccinations.

The system to compensate for damage caused by side effects of vaccination by insurance will eventually avoid insurance coverage for vaccination-related people due to unclear limits of liability surrounding vaccination, making it difficult to compensate for damage through insurance money.

The Republic of Korea has introduced NVICP in 1994 but globally, Germany was the first to introduce this policy in 1966. The United States and Taiwan were both established NVICPs in 1988. More countries without NVICP are moving towards implementing NVICPs due to the urgency of reaching herd immunity through COVID-19 vaccinations. In January 2019, South Korean President Moon, Jae-in vowed that the government will take full responsibilities for any occurring COVID-19 side effects by expanding the current compensation coverages for vaccine injuries (Seo, 2021). However, with causal link between the side effects and the vaccine ambiguous and still under research, the vaccine skepticism is growing. The Korea Disease Control and Prevention Agency (KDCA)'s data indicates that out of 908 alleged vaccine injury claims with serious injuries, 678 cases resulted in deaths following vaccinations, and of those cases, only two deaths and five critical cases were acknowledged as related ranging from possibly, probably, to definitely (Lee, 2021).

1.2 Purpose of the Study

By conducting a comparative analysis on vaccine injury compensation programs of three countries: the United States of America, Taiwan, and Republic of Korea, this paper will examine factors ranging from historical backgrounds of VICP implementation to the successes and challenges of vaccine injury claims. United States of America was chosen because of its Countermeasures Injury Compensation Program (hereinafter, CICP), a year-round operating program that currently handles COVID-19 vaccine injuries. Taiwan was selected because it is within the Asian region which means research findings are likely to be more similar in cultural traits with the Republic of Korea, and another reason was that Taiwan started its vaccine injury compensation program in the same year as the United States of America.

The goal of this study is 1) to compare compensation program structures between the three countries to propose an amendment to the current system, 2) to help the public to better understand NVICP process and to better access information regarding NVICP, and 3) to provide grounds for a new emergency vaccine injury compensation program for future pandemics. I believe that through this study I will be able to provide evidence and guidance to strengthening KNVICP, a measure that can be trusted.

1.3 Method of the Study

This study was conducted using qualitative comparative analysis with the application of Most Similar Systems Design (MSSD) to identify similarities and differences between the Korean National Vaccine Injury Compensation Program (KNVICP) and VICPs of the U.S. and Taiwan. Countries were selected based on the factors that include socio-cultural similarities, VICP introduction timing, and potential contributions of each programs' weaknesses and strengths to enhancing the Korean VICP.

According to NUPI, the comparative method entails examining one item of study in comparison to another. In most cases, the object of study is contrasted over distance and/or time. Quantitative and qualitative comparative approaches are both possible. However, there's usually a tradeoff: the more cases to analyze, the fewer similar variables there will be, and vice versa. When looking for patterns of similarities and differences, but also explaining continuity and change, the comparative technique is commonly adopted. The goal of Most Similar Systems Design is to compare similar cases that differ in dependent variables with the assumption that independent variables will help explain the presence of the dependent variable, or lack thereof.

The data and literature needed for this study were processed by gathering and analyzing published journal articles, news media, government publications, governmental and other official Youtube channels, government websites, published books, legislations regarding vaccine injury. The main databases were EBSCOhost and PubMed Central and keywords used for research include "vaccine injury", "vaccine disability", "vaccine related casualties", "vaccine injury compensation program", "vaccine law", "no-fault compensation", "vaccine adverse event", and "vaccine injury claim". For the application of vaccine injury compensation process in times of national emergencies like COVID-19, the same research method was employed as above. This paper aimed to verify structural and legal details of VICPs in the United States of America, Taiwan, and the Republic of Korea.

2 Comparison of VICPs

2.1 Overview of Compensation Programs

2.1.1 United States of America

An influenza outbreak swept the globe in 1918, killing more than 2 million people worldwide. Following these events, the issue of vaccinations against infectious diseases has been a global concern. When U.S. soldiers stationed in Fort Dix, New Jersey, died in early 1976, authorities at the Centers for Disease Control and Prevention (CDC) in the United States were worried that this was the reemergence of the 1918 pandemic. At CDC's request, the federal government began a swine flu vaccination program (Dehner, 2010).

Execution of national-scale policies required mass production of vaccines by the pharmaceutical industry. US government authorities promised vaccine manufacturers some form of immunity in exchange for their cooperation, assuming that vaccine manufacturers would be willing to provide the vaccines required. Congress passed the Swine Flu Act in response to the impending flu season. All legal obligations of vaccine makers and operators were shifted to the federal government under this act. This meant that under the Swine Flu Act, the US federal government has agreed to take full legal responsibility for any injuries or deaths caused by the administration of the swine influenza vaccine (Gaskins, 1980).

Vaccination began on October 1, 1976, and over 45 million individuals have been immunized since then (Attwell, Drisland and Leask, 2019). However, only a few fatal influenza cases occurred when comprehensive vaccination measures were in place, and the implementation was halted on December 16, 1976. Reasons were that the infectious cold was unlikely to spread widely, and Guillain-Barre syndrome, multiple neuroses, has been

documented in every 100,000 persons who have been vaccinated (Centers for Disease Control and Prevention, 2009). *Guillain-Barre Syndrome* is a polyneuritis that can cause paralysis from a viral infection. Patients who acquired Guillain-Barré Syndrome after getting the swine influenza vaccination were required to file a claim for damages against the federal government under the Swine Flu Act, and the federal government rewarded the Guillain-Barré Syndrome victims. However, despite the prophylactic intention of controlling a pandemic, the swine flu vaccination campaign in the States turned out to be a total fiasco created by the Centers for Disease Control and Prevention (CDC), and the US government officials rushed to decide on a faulty prediction of the Fort Dix situation. It was a hastily made misjudgment.

Before 1987, persons wounded by vaccinations in the United States had no alternative except to take their chances in court and seek compensation from the manufacturers. It became impossible for vaccine manufacturers to forecast their exposure to litigation without a compensation structure. As a result, manufacturers and their insurers raised prices, assuming worst-case scenarios that included waves of lawsuits and a causal association between injuries and vaccines. This resulted in soaring prices, a lack of vaccine production, and a decline in vaccine research overall. In addition, several minor vaccine producers have exited out of the market. However, vaccine adverse events took a turn and nearly fully funneled through a no-fault compensation system operated through the United States Court of Federal Claims with the implementation of the National Childhood Vaccine Injury Act of 1986 (Keane et al., 2019).

The VICP, which has been in operation since October 1988, has played a significant role in stabilizing the US vaccine industry by providing liability protection to both vaccine manufacturers and healthcare providers. The no-fault compensation rule addresses the litigation system's limitations that require proof of negligence or liability for the loss of body function or even life. Other practical advantages contribute to the effectiveness of national immunization programs and, ultimately, to public health. For example, no-fault compensations schemes encourage innovations and developments of

vaccine industry by exempting researchers and manufacturers of any financial liabilities due to personal injury claims regarding their products. Indeed, this was one of the driving forces behind the introduction of federal VICP in 1986 (Attwell, Drisland and Leask, 2019).

The United States Department of Health and Human Services (HHS), the United States Department of Justice, and the United States Court of Federal Claims (CFC) are the three government entities involved in VICP. The Health Resources and Services Administration, an agency under the Department of Health and Human Services, oversees the program. Claimants may submit a petition with the HHS and the CFC, either through a legal representation or on their own, to begin the review and adjudication process[1].

The process begins when a petition is filed. The Clerk's Office receives each claim at the U.S. Court of Federal Claims. The process of filing a claim and reviewing the case is quite unwieldy because special masters of the review committee need to review, make conclusions, make recommendations of every case claimant file. According to the United States Courts' official Youtube clip "Vaccine Injury Program and the U.S. Court of Federal Claims, in 2015, 70-80% of claims were settled, approximately 10% or higher number of cases were dismissed due to defects of the claims which include the statute of limitation problems, burden of proof, or not having any expert to support the case, and the rest of the cases (20%) are litigated. In the United States, claims go through what looks like a trial but are termed hearing because "rules of evidence" are not applied directly. All hearings are legally closed to the public. Office of special masters is based in Washington D.C., but they travel to different states at the convenience of the claimants.

[1] Health Resources & Services Administration. The United States of America. https://www.hrsa.gov/vaccine-compensation

2.1.2 Taiwan

Following an incident in 1986 involving oral polio vaccines that resulted in a polio case, the Department of Health (DOH) requested representatives from pharmaceutics, law, and labor unions to study the systems of Europe, America, and other developed countries, and as a result, the vaccine injury compensation fund was established in June 1988. The Vaccine Injury Compensation Program Working Group (VICPWG) of the Department of Health was established in 1992. The goal of this compensation mechanism was that if anyone who had a vaccine-related adverse reactions that resulted in death, physical and mental injuries, or other serious illness would be able to receive adequate compensation in a timely manner after a professional review by experts to remove any doubts or fear the public may have about vaccine side effects, and to ultimately enhance vaccination rates.

Whether vaccines are publicly or self-funded in Taiwan, all injuries related to these vaccines can be compensated through the same system (Keane et al., 2019). All claims are made to the relevant jurisdictional health bureaus, then progressed to the Centers for Disease Control within the Ministry of Health and Welfare, and then to the Vaccine Injury Compensation Program Working Group (VICPWG) for further review and deliberation. The last part of the review process is through the VICPWG where a panel of 19 to 25 part-time experts reaches a decision, the notification of results and claimant's request for payment are met. Before the decision is out, VICPWG will review all medical records, test results, medical treatments given, the course of individual's physical and mental injuries, and the known characteristics of vaccine to discover and determine all possibilities between the alleged injury and vaccination.

There is a two-year filing deadline from the date of the injury and a five-year filing deadline from the day the alleged victim received the vaccination, which may serve as a cost-control measure within the VICP budget. Furthermore, there are limits to the amount awarded for a given injury which will be discussed later in this study.

2.1.3 Republic of Korea

In 1994, two incidents of mortality were reported in the Korean media following the Japanese encephalitis vaccine. Vaccination safety thus became a societal problem, and as public concern about the vaccine grew, so did the demand for national vaccine safety management. As a response, the Korean National Vaccine Injury Compensation Program (KVICP) was introduced in January 1995, creating the Korea Advisory Committee on Vaccine Injury Compensation (KACVIC) to evaluate whether vaccinations caused an adverse event. In 1999, a surveillance system for Adverse Events Following Immunization (AEFI) was established, and in 2000, adverse event reporting standards and responsibilities were specified. Through these processes, Korea developed a more systematic way of monitoring vaccine injuries (Kim et al., 2017).

According to the criteria presented in the Korean Infectious Disease Control and Prevention Act[2] (hereinafter the IDCPA), Korea's no-fault compensation program is a standalone initiative, which means that it has a confined list of eligible vaccines recommended by the national vaccination program. The NVICP does not cover vaccine injuries caused by vaccinations that individuals voluntarily purchase.

Korea Advisory Committee on Vaccine Injury Compensation (KACVIC) is comprised of 15 experts, and its goals are 1) to review the causal relationship between adverse reactions and vaccine administration 2) to examine whether each case complies with the compensation criteria. The KACVIC has quarterly meetings to evaluate claims submitted (Looker and Kelly, 2011).

The Korea Centers for Disease Control and Prevention has been in charge of the national immune safety management system, which includes obtaining high-quality

[2] Reliable Ministry of Government legislation Korean Law Information Center. INFECTIOUS DISEASE CONTROL AND PREVENTION ACT (2020).

vaccines, monitoring and conducting epidemiological investigations of serious adverse events, and managing a vaccine injury compensation system as part of the Korea National Immunization Program. Since the Korean National Vaccine Injury Compensation Program (KNVICP) in 1994, it has been a vital and necessary action to reassure the safety of vaccines for both the general population and the individuals involved in vaccine production and administration. To implement vaccination programs successfully, we must address the problem of vaccine safety and overcome it to provide herd immunity and protect the population from diseases.

2.2 Assessment of Causality

No-fault vaccine-injury compensation programs are grounded on the assumption that the adverse event is due to an inevitable risk associated with vaccines, not to a specific individual or entity involved in the immunization process. Assessing a causal relationship between vaccination and a specific injury is crucial for all compensation programs. The conventional approach of demonstrating causality in research and epidemiology may differ significantly from how tort law shows causation. The Bradford Hill criteria[3] are the most widely recognized standards for determining epidemiological causality (Looker and Kelly, 2011). While these criteria may not serve as a comprehensive checklist for assessing causality, they provide a framework for differentiating between causal and non-causal explanations for documented relationships between adverse events and vaccines. There is no universally agreed definition of causality, despite its importance.

[3] Bradford Hill's criteria in vaccinations can be summarized as follows:
1) demonstration of a strong causal association between the vaccine and the adverse events, 2) consistency of findings across sampling sites and methodologies, 3) demonstration of vaccine's specificity in terms of the adverse events it causes, 4) demonstration of the appropriate sequence of events that shows adverse outcome followed vaccination, 5) the demonstration of a dose-response relationship, in which increasing the amount of the vaccine leads to a negative consequence 6) the evidence of a biologic reasoning, such that it is reasonable to believe that the causal agent is responsible for the outcome 7) coherence of the data, in the sense that the causation argument aligns with existing information 8) experimental evidence, and 9) evidence of similar observations (Reekum et al., 2001).

2.2.1 United States of America

While these Bradford Hill criteria may not serve as a definitive checklist for determining causality, they provide a framework for differentiating between causal and non-causal explanations for documented relationships of adverse events and vaccines. Despite its importance, there is no commonly agreed definition of causality (Looker and Kelly, 2011).

There are three ways to be eligible for vaccine injury compensation:

1. A petitioner must establish that an injury listed on the vaccine injury table happened within the specified time interval.
2. Prove the causal relationship between the vaccine and the alleged health condition.
3. Prove that the vaccine aggravated a preexisting health condition.

If a petitioner cannot prove a table injury, or if no table injuries have been reported for a given vaccine, the petitioner may choose to prove causation. The petitioner must additionally prove that the consequences of the injury

1. persisted 6 months after administering a vaccination,
2. resulted in a hospital stay or a surgery, or
3. ended in death, in addition to meeting one of the three compensation criteria.

If the court judges that there is more evidence of a non-vaccine reason for the injury, petitioners are not eligible for compensation. A HHS physician examines each petition's medical data to see if the medical conditions for compensation are met. Based on the evaluations, a US Department of Justice attorney will submit the HHS' position to one of eight special masters, who are attorneys selected by the CFC who have expertise in legal and medical concerns. The special master has the authority to approve settlements agreed by the parties, and they make the final decision of VICP.

The amount of the award is generally negotiated between the U.S. Department of Justice and the petitioner or petitioner's legal counsel if a petition is determined eligible for compensation, either by the HHS admitting the case or by a special master's ruling. If the parties cannot reach an agreement, the special master will have to decide on compensation. Successful petitioners may be compensated for unreimbursed past and future medical bills, lost wages, and pain and suffering. Even if the petitioner is not deemed eligible for compensation, the program reimburses attorneys' fees and costs if the claim was submitted in good faith and on a fair basis. As a result, while a petitioner does not require an attorney to submit a claim, the majority of petitioners do so (Cook and Evans, 2011).

2.2.2 Taiwan

The standard of proof employed in Taiwan categorizes the causal relationship into three types: an injury can either be related, possibly related, or unrelated; only unrelated injuries are rejected. This model is similar to, but not the same as the WHO recommendations. According to Article 6 of the regulations of the Taiwanese Ministry of Health and Welfare, a claimant needs to attach a "proof of injury or other information sufficient to show injury to the municipal or county/city competent authority (hereinafter, central competent authority) at where the alleged victim received the vaccination" when submitting an application for vaccine injury compensation[4].

Taiwan operates a more relaxed standard of proof than the U.S. The standard of proof used appears to limit the number of awards and costs of compensation, however, during 15 years, 40% of VICP claims were successful. Where there is an expert consensus on vaccine-related injuries, this can increase the number of successful claimants for a

[4] Ministry of Health and Welfare. (2021, February 18). Regulations Governing Collection and Review of Vaccine Injury Compensation Fund. Taipei..

specific vaccine and its associated injuries. The degree of scientific evidence can affect the standard of proof and, therefore, have an impact on the number of awards. If there is little evidence on the injuries associated with a vaccine, there is a high proportion of rejected cases (Keane et al., 2019).

2.2.3 Republic of Korea

Korean VICP's causality assessment criteria consist of five categories that are modified based on the World Health Organization's causality assessment criteria: definitely related, probably related, possibly related, unlikely to be related, and definitely not related. Compensations are made for the cases that are classified as definitely, probably, and possibly related.

However, in 2018, the WHO has streamlined its causality assessment criteria to only three: consistent, inconsistent, and indeterminate causal associations to vaccines (WHO, 2018). It is classified as "indeterminate" if a temporal link is consistent but there is a lack of definite evidence for a causal link or when evidence shows conflicting tendencies of consistency and inconsistency. While Korean the criteria employ five categories to determine causality, the compensation amounts for situations in the "certainly related," "probably related," and "possibly related" categories are the same; the claimed amount is completely reimbursed in all of these circumstances. Cases characterized as "probably not related" and "definitely not related," on the other hand, did not show causality, and so reimbursement for the amount claimed was completely rejected (Kim et al., 2017).

Table 1. Causality Assessment Criteria (WHO-ROK)

Republic of Korea Causality Assessment Criteria for Vaccine Injuries		WHO Causality Assessment Criteria for Vaccine Injuries	
Definite	There is definite evidence of inoculation with the vaccine; temporal proximity in which an adverse event appeared; causal relationship between the event and vaccination rather than other causes is accepted; and the adverse event is the known reaction to the vaccine.	Very likely, certain	Clinical event with a plausible time relationship to vaccine administration, and which cannot be explained by concurrent disease or other drugs or chemicals.
Probable	There is definite evidence of inoculation with the vaccine; temporal proximity in which an adverse event appeared; and causal relationship between the event and vaccination rather than other causes is accepted.	Probable	Clinical event with a reasonable time relationship to vaccine administration, and is unlikely to be attributed to concurrent disease or other drugs or chemicals.
Possible	There is definite evidence of inoculation with the vaccine; temporal proximity in which an adverse event appeared; it is recognized at the same level of probability that the reaction may be due to vaccination or other reasons.	Possible	Clinical event with a reasonable time relationship to vaccine administration, but which could also be explained by concurrent disease or other drugs or chemicals.
Unlikely	There is definite evidence of inoculation with the vaccine; temporal proximity is not accepted when adverse events appeared, if the causal relationship between the event and vaccine is unclear.	Unlikely	Clinical event whose time relationship to vaccine administration makes a causal connection improbable, but which could plausibly be explained by underlying disease or other drugs or chemicals.
Definitely not related	There is absence of evidence of vaccine inoculation; or absence of proximity of the temporal sequence in which adverse events appeared; or presence of obvious causes resulted in the event.	Unrelated	Clinical event with an incompatible time relationship to vaccine administration, and which could be explained by underlying disease or other drugs or chemicals.

2.2.4 Findings

Table 2. Comparison of Causality Assessment Criteria

WHO[5]	ROK	Taiwan	USA
Very likely, Certain	Definite	Related	Details Unknown
Probable, Likely	Probable	Possibly Related	
Possible	Possibly	Unrelated	
Unlikely	Unlikely		
Unclassifiable	Unrelated		

All three programs reviewed require a standard of proof showing a causal link between vaccination and injury. According to Looker and Kelly, most compensation programs use the "balance of probabilities" approach, which presumes that the vaccine caused the injury "more likely than not" based on the nature of the injury, the consistency of the time interval from vaccination, the existing medical proof establishing an association between the injury and the vaccine, and other supporting information (2011). A panel of specialists in the remaining programs decides the standard of proof (Looker and Kelly, 2011). However, Taiwan and United States of America had limited information on causality assessment criteria, though they must have referred to WHO guidelines and other causality assessment tools. U.S. government website did not provide details of the criteria.

5 The Uppsala Monitoring Centre. (n.d.). *Who causality assessment? - world health organization*. World Health Organization. Retrieved January 7, 2022, from https://www.who.int/medicines/areas/quality_safety/safety_efficacy/WHOcausality_assessment.pdf

2.3 Understanding Vaccine Injury Tables

2.3.1 United States of America

As of January 2011, the VICP had paid out over $2.1 billion in compensation to over 2500 families and individuals (Cook and Evans, 2011). The vaccine market is strong, and the VICP continues to carry out Congress's goal by offering an accessible and efficient alternative for those who have been injured by certain childhood vaccines, as well as guaranteeing the vaccine industry's sustainability (Cook and Evans, 2011).

The VICP covers all vaccinations recommended for routine administration to children by the Centers for Disease Control and Prevention. Diphtheria, tetanus, and pertussis (DTP, DTaP, TdaP, DT, TT, or Td), measles-mumps-rubella (MMR or any component), polio (oral polio vaccine [OPV] or inactivated polio vaccine [IPV]), hepatitis A, hepatitis B, Hemophilus influenza type b (Hib), varicella (chickenpox), rotavirus, pneumococcal conjugate, trivalent influenza (given annually), meningococcus, and human papillomavirus (HPV), whether administered individually or in combination. Although the VICP only covers vaccinations approved for routine use in children, there are no age limitations for filing for a claim. In reality, adult claims account for more than half of all claims received each year (Cook and Evans, 2011).

Table 3. Vaccine Injury Table - Part 1(USA)

Vaccine	Adverse Events	Interval After Immunization
Vaccines Containing tetanus toxoid (e.g. DTaP, DTP, DT Td, or TT)	Anaphylaxis	≤ 4 hrs
	Brachial Neuritis	2-28 days (not less than 2 days and not more than 28 days)
	Shoulder Injury Related to Vaccine Administration	≤48 hrs
	Vasovagal syncope	≤1 hr
Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)	Anaphylaxis	≤ 4 hrs
	Brachial Neuritis	≤ 72 hrs
	Shoulder Injury Related to Vaccine Administration	≤48 hrs
	Vasovagal syncope	≤1 hr
Vaccines containing measles, mumps, and rubella virus or any of its components (e.g., MMR, MM, MMRV)	Anaphylaxis	≤4 hours
	Encephalopathy or encephalitis	5-15 days (not less than 5 days and not more than 15 days)
	Shoulder Injury Related to Vaccine Administration	≤48 hours.
	Vasovagal syncope	≤1 hour
Vaccines containing rubella virus (e.g., MMR, MMRV)	Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days).
Vaccines containing measles virus (e.g., MMR, MM, MMRV)	Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days).
	Vaccine-Strain Measles Viral Disease in an immunodeficient recipient	Not applicable
	- Vaccine-strain virus identified	≤12 months.
	- If strain determination is not done or if laboratory testing is inconclusive	

Table 4. Vaccine Injury Table – Part 2 (USA)

Vaccine	Adverse Events	Interval After Immunization
Vaccines containing polio live virus (OPV)	Paralytic Polio - in a non-immunodeficient recipient - in an immunodeficient recipient - in a vaccine associated community case Vaccine-Strain Polio Viral Infection - in a non-immunodeficient recipient - in an immunodeficient recipient - in a vaccine associated community case	 ≤30 days ≤6 months. Not applicable. ≤30 days ≤6 months Not applicable.
Vaccines containing polio inactivated virus (e.g., IPV)	Anaphylaxis Shoulder Injury Related to Vaccine Administration Vasovagal syncope	≤4 hours ≤48 hours. ≤1 hour
Hepatitis B vaccines	Anaphylaxis Shoulder Injury Related to Vaccine Administration Vasovagal syncope	≤4 hours ≤48 hours. ≤1 hour
Haemophilus influenzae type b (Hib) vaccines	Shoulder Injury Related to Vaccine Administration Vasovagal syncope	≤48 hours. ≤1 hour

2.3.2 Taiwan

The VICPWG experts are mostly infection specialists, immunologists, pathologists, neurologists, and one-third of the members account for legal and social justice experts. Members will be appointed for a two-year term and re-appointed when the current term expires. A person with the same or comparable skill as the original member may be appointed to fill the vacancy and serve until the original term expires if there is a vacancy during a member's appointment. The mission of the Working Group is 1) to review vaccine injury compensation claim applications 2) to assess the causal relationship between the alleged injury and vaccination 3) to determine the extent of the injury and to decide on the amount of compensation, and 4) to determine other matters in the compensation process (Ministry of Health and Welfare, 2021).

Vaccine injury table embedded with causality assessment criteria is shown below:

Table 5. Criteria of Compensation for Vaccine Injury (Taiwan)[6]

Type of compensation	Criteria			Amount of Compensation (NT$100,000)
	Definition/ Degree of Disability		Causality Conclusion	
Compensation for Death	-		Vaccine related	50 ~ 600
			Possibly vaccine related	30 ~ 350
Compensation for Disability	Determined by the types and degrees of disability set forth in regulations for the protection of physically and mentally disabled.	4-extremely severe	Vaccine related	50 ~ 600
			Possibly vaccine related	30 ~ 350
		3-severe	Vaccine related	30 ~ 500
			Possibly vaccine related	20 ~ 300
		2-moderate	Vaccine related	20 ~ 400
			Possibly vaccine related	10 ~ 250
		1-mild	Vaccine related	10 ~ 250
			Possibly vaccine related	5 ~ 200
Compensation for Severe Illness	Illnesses determined by the Catastrophic Illness list from the National Health insurance or based on severe adverse reactions of medicament as defined in the Regulations for Reporting Severe Adverse Reactions of Medicaments, which do not reach the definition of disability.		Vaccine related	1 ~ 300
			Possibly vaccine related	1 ~ 120
Compensation for Other Adverse Reactions	Other adverse reactions not meeting the definition of severe illnesses. However, mild, commonly seen or expected adverse reactions of vaccination will not be compensated.		Vaccine related/ Possibly vaccine related	0 ~ 20

[6] Wang P-C. (2015) Updates on Vaccine Injury Compensation Program in Taiwan and program evaluation. Epidemiology Bulletin 2015;31(18):149-58. https://doi.org/10.6525/TEB.20150922.31(18).001

2.3.3 Republic of Korea

In the Republic of Korea, there are two different programs covering injuries arising from vaccines listed in the national immunization program (NIP) and non-NIP vaccines (Mungwira et al., 2020). NIP vaccinations are supported by the government, whereas pharmaceutical firms or market permission holders pay for non-NIP vaccine injuries. Claimants are compensated in all programs with either (or a combination of): a lump-sum of money; recompense calculated based on medical costs and expenses, lost income or potential earnings; or recompense calculated based on non-monetary criteria such as pain and suffering, mental trauma, permanent impairment, or loss of function. Disability pensions, survivor pensions, and death benefits are some of the many benefits available (Mungwira et al., 2020).

All of the no-fault compensation plans included a standard of proof that there was a causal link between vaccination and injury. Claimants are compensated in one of two ways: lump-sum payments; amounts calculated based on healthcare costs and expenses, loss of earnings or earning potential, pain and suffering, psychological distress, permanent impairment or impaired functions; or a combination of the following. Vaccine injury petitioners in most countries have the option of pursuing damages through a civil lawsuit or a compensation plan, but not both at the same time.

The Korea Advisory Committee on Vaccine Injury Compensation (KACVIC), a quarterly review committee of 15 expert members, evaluates and determines whether each claim case fits the causality criteria and vaccine injury table. KACVIC, which has 15 expert members, examines whether each case fits the threshold for compensation by reviewing the causal relationship between adverse events and vaccine administration.

Table 6. Vaccine Injury Table (ROK)

Vaccine	Adverse Events	Interval After Immunization
DTaP, Tdap, Td, Japanese encephalitis vaccine, Korean hemorrhagic fever vaccine	Anaphylaxis	≤ 24 hr
	Encephalitis, encephalopathy	≤ 7 days
	Other central nervous system symptoms	≤ 7 days
	Sequelae due to 1-3	No limit
	Severe edema accompanying local pain	≤ 7 days
	Brachial neuritis or peripheral neuritis	≤ 28 days
	Fever ≥ 39°C	≤ 2 days
	Other adverse events suspected as related with immunization	No limit
MMR	Anaphylaxis	≤ 24 hr
	Encephalitis, encephalopathy	≤ 21 days
	Other central nervous system symptoms	≤ 21 days
	Sequelae due to 1-3	No limit
	Thrombocytopenic purpura	7-30 days
	Chronic arthritis	≤ 42 days
	Other adverse events suspected as related with immunization	No limit
BCG	Lymphadenopathy (diameter≥ 1 cm)	≤ 1 yr
	Local mass in inoculation site	≤ 6 mo
	Osteitis, osteomyelitis	≤ 6 mo
	Systemic miliary BCG infection	≤ 6 mo
	Other adverse events suspected as related with immunization	No limit

2.4 Legislations in VICP

The VICP set up a no-fault alternative to the traditional tort system (Cook and Evans, 2011). This reduced the liability for vaccine manufacturers in a highly litigious society and facilitated more rapid compensation for injured individuals. Although we cannot explore the counterfactual, the strategy of creating the VICP appears successful based on historically high immunization rates and low rates of most vaccine-preventable diseases (Meissner, Nair and Plotkin, 2019; Conway and Green, 2011). Furthermore, regardless of whether the claims are for Vaccine Injury Table-related injuries, the legislation compels all petitioners alleging vaccine injuries by VICP-covered vaccines to go through the VICP procedure before they can access the conventional tort system. This policy continues to aid in maintaining vaccine producers in the market, ensuring a steady supply of vaccines, and giving partial incentives for vaccine research through legal protection (Thompson, Orenstein and Hinman, 2020; Cook and Evans, 2011).

2.4.1. United States of America[7]

[7] **PART 100—VACCINE INJURY COMPENSATION**

■ 1. The authority citation for 42 CFR part 100 continues to read as follows:

Authority: Secs. 312 and 313 of Public Law 99–660 (42 U.S.C. 300aa–1 note); 42 U.S.C. 300aa–10 to 300aa–34; 26 U.S.C. 4132(a); and sec. 13632(a)(3) of Public Law 103–66.

■ 2. In § 100.3, revise paragraph (a) and remove paragraphs (c)(10) and (13) and (e)(8). The revision reads as follows:

§ 100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa–14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving

Considering the initial Vaccine Injury Table, in 1987. Congress established an initial time-limited federal excise tax "based on the number of anticipated doses and current scientific views about the relative risk from each vaccine" (Treadway Johnson, Drew and Miletich, 1998). It set the nominal amounts per dose of $4.56 for diphtheria-pertussis-tetanus (DPT), $4.44 for measles-mumps-rubella (MMR), $0.29 for oral poliovirus vaccine (OPV), and $0.06 for diphtheria-tetanus (DT) from January, 1988, to December 31, 1992 for injuries incurred after September 30, 1988 and before October 1, 1992[89]. Congress also appropriated funds for claims for injuries that occurred prior to October 1, 1988 (pre-Act cases), to support the initial phases of the program (Thompson, Orenstein and Hinman, 2020). After a brief lapse (with no tax applied in early 1993), on August 10, 1993, the federal excise tax became permanent and resumed at the prior nominal cost levels, and the creation of the Vaccines for Children (VFC) Program established a mechanism for ensuring universal pediatric immunization coverage in the U.S.[10].

The Taxpayer Relief Act of 1997[1112] subsequently lowered the federal excise tax to a nominal amount of $0.75 per dose for each vaccine-preventable disease (i.e., $2.25 per MMR dose since MMR prevents three diseases), and the tax continues at that nominal amount to date (e.g., the actual value of the tax decreases over time due to the use of a fixed nominal fee despite inflation). Manufacturers pay these excise taxes into the Vaccine Injury

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compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the Qualifications and Aids to Interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the Qualifications and Aids to Interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).[7]

[8] 100th U.S. Congress (1987–8). H.R.3545 - Omnibus Budget Reconciliation Act of 1987.

[9] Department of the Treasury Internal Revenue Service. (n.d.). *Internal Revenue Cumulative Bulletin 1987-3*. govinfo.

[10] 103rd U.S. Congress (1993–4). H.R.2264 - Omnibus Budget Reconciliation Act of 1993. t

[11] *Taxpayer relief act of 1997*. Congress.Gov. (1997, August 5).

[12] 105th Congress (1997–8). Public Law 34, Taxpayer Relief Act of 1997.

Compensation Trust Fund. In addition to paying for injury compensation and legal fees, the trust fund also provides financial support for VICP-related administrative expenses incurred by the Department of Health and Human Services (DHHS), Department of Justice, and the Claims Court (estimated total of approximately $10 million per year in the mid-1990s) (Thompson, Orenstein and Hinman, 2020).

If the vaccine category is indicated for routine use in children (e.g., influenza vaccination), the VICP covers claims from people of all ages; however, it does not cover claims for vaccines that are only targeted at adults (e.g., herpes zoster vaccines for shingles). As a result, for vaccinations indicated just for adults, there is no reimbursement system similar to VICP in the United States. The 21st Century Cures Act (Public Law 114-255) expanded VICP coverage to include vaccines recommended for use in pregnant women in 2016 and clearly stated the VICP funds to cover alleged injuries incurred to both pregnant women and their children who were in utero during the pregnancies.

2.4.2 Taiwan

The “Communicable Disease Control Act” was implemented to prevent and control communicable diseases and promote policies that ensure safety of the public health. According to the Taiwan Public Health Report 2010, Article 27 of the Communicable Disease Control Act was amended and made public in order to provide legal grounds for the Taiwanese national vaccine fund[13].

> To ensure appropriate compensation for victims of vaccinations and the implementation of national immunization policies, the DOH amended and promulgated Article 7 of the Regulations Governing Collection and Review of Relief Fund for Victims of Immunization”.
>
> - Taiwan Public Health Report 2010. pg. 36

If the claimant is not pleased with the judgment or the amount of the award compensated, the claimant has the right to submit an appeal with the Petitions and Appeals Committee, which is accountable for adjudicating appeals of government decisions, within 30 days after obtaining the decision. If the claimant still does not concur with the Petitions and Appeals Committee’s decision, he or she can initiate a lawsuit against the Ministry of Health and Welfare. The Petitions and Appeals Committee has yet to overturn a VICPWG ruling on injury causation; however, an appeal against a judgment in which the injured individual was not awarded even though the injury was caused by vaccination was successful (Wang, 2015; Macleod et al., 2017; Keane et al., 2019).

To sustain Taiwan’s immunization policy, an "Immunization Fund" was established in accordance with Article 27 of the Communicable Disease Control Act in 2010. The Fund serves as a stable funding source to implement a new immunization policy each year. A “National Immunization Information System” was established to monitor and track the immunization status of young children. To deal with the side effects of

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[13] Department of Health. (2010). *Taiwan Public Health Report 2010*. Department of Health R.O.C (Taiwan).

immunizations, the government has established the “Vaccine Injury Compensation Program (VICP)” to enable victims to receive the assistance they are legally entitled to (Ministry of Health and Welfare, 2019).

2.4.3. Republic of Korea[14]

[14] **INFECTIOUS DISEASE CONTROL AND PREVENTION ACT**

[Enforcement Date 12. Aug, 2020.] [Act No.17475, 12. Aug, 2020., Partial Amendment]
CHAPTER I GENERAL PROVISIONS

Article 2 (Definitions)

17. The term "epidemiological investigation" means the activities of investigating the number of cases involving patients of an infectious disease, etc. and of tracing the sources of their infection, etc., if such cases occur, in order to contain such infectious diseases and to prevent their spread, and the activities of examining the causes of adverse reactions, if such cases occur after vaccinations have been taken against infectious diseases or if it is unclear whether a disease is infectious but it is necessary to investigate the cause thereof;
18. The term "adverse reaction to a vaccination" means any symptom or disease that may be caused by a vaccination, which is related to such vaccination in terms of time;[14]

Article 71 (Compensation by the State for Injury Caused by Vaccination)(1) Where a person who has been vaccinated pursuant to Articles 24 and 25, or a person who has been administered a preventive and therapeutic medicine pursuant to Article 40 (2) contracts a disease, becomes disabled, or dies due to such vaccination or preventive and therapeutic medicine, the State shall pay the following compensation according to the standards and procedures prescribed by Presidential Decree:

1. A person who receives treatment for a disease: All medical expenses and a fixed amount of nursing expenses;
2. A person who becomes disabled: A lump-sum compensation;
3. A deceased person: A lump-sum compensation for the bereaved family members and funeral expenses prescribed by Presidential Decree.

(2) A disease, disability, or death eligible for the compensation under paragraph (1) shall be limited to cases recognized by the Commissioner of the Korea Disease Control and Prevention Agency, in which injury is caused by vaccination or administration of a preventive and therapeutic medicine, regardless of abnormality of the relevant vaccine, or negligence of the person who performed vaccination or administered the relevant preventive or therapeutic medicine. <Amended on Jan. 18, 2010; Aug. 11, 2020>

(3) The Commissioner of the Korea Disease Control and Prevention Agency shall determine whether a filed case is applicable to a disease, disability, or death under paragraph (2) within 120 days from the

According to the criteria presented in the Korean Infectious Disease Control and Prevention Act[15] (hereinafter the IDCPA), Korea's no-fault compensation program is a standalone initiative, which means that it has a confined list of eligible vaccines recommended by the national vaccination program. The NVICP seems comparatively more restricted than Taiwan because injury claim cases are only eligible for compensation when the alleged victim's copayment due to the adverse reaction exceeds 300,000 KRW (approx. US $266) (Kim et al., 2017). In other words, the KVICP's objective is to compensate for moderate to severe vaccine side effects and not for a series of minor events.

In Article 54-2 of the Infectious Disease Prevention Act, "① The State shall compensate for standards and procedures prescribed by Presidential Decree when a person who has been vaccinated pursuant to Articles 10-2 through 12 becomes ill, becomes disabled or dies as a result of the vaccination. In accordance with the following, compensation shall be made. 1. For those who have received medical treatment due to illness, the total medical expenses and flat-rate nursing expenses. For those who become disabled, temporary compensation 3. For those who have died, lump-sum compensation and funeral expenses for the bereaved family as prescribed by Presidential Decree ② Vaccinations under Paragraph 1 Disease, disability, or death caused by the disease refers to a case recognized by the Minister of Health, Welfare and Family Affairs as damage

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date a claim for compensation under paragraph (1) is filed. In such cases, he/she shall hear the opinions of the Committee in advance. <Amended on Jan. 18, 2010; Aug. 11, 2020>
(4) Matters necessary for the claims for compensation under paragraph (1), the methods of and procedures for determination under paragraph (3), and other relevant matters shall be prescribed by Presidential Decree.

[15] Reliable Ministry of Government legislation Korean Law Information Center. INFECTIOUS DISEASE CONTROL AND PREVENTION ACT (2020).

caused by the vaccination, regardless of whether there is an abnormality in the vaccination drug or the negligence of the person who took the vaccination, etc. In particular, disease, disability, or death caused by vaccination is considered a damage caused by the vaccination regardless of who is at fault. The principle behind vaccine injury compensation is given based on a no-fault liability principle.

Table 7: Comparison of VICPs in USA, Taiwan, and ROK [16]

	United States of America	Taiwan[17]	Republic of Korea
Year (revised)	1988	1988	1994
Process and Decision Making	Department of Justice, Department of Health and Human Services, Office of Special Masters, and the United States Court of Federal Claims (aka Vaccine Court)	Ministry of Health and Welfare (MoHW), Vaccine Injury Compensation Program Working Group (VICPWG)	Korea Disease Control and Prevention Agency (KDCA), Korea Advisory Committee on Vaccine Injury Compensation (KACVIC)
Administration and Funding	Tax on every vaccine dose distributed	Tax on every vaccine dose distributed plus local Government funds *	Government
Eligibility	Any injury likely caused by the vaccine	Alleged Victim or Legal Heir(s) for a death case	Patient must have spent at least 300,000 South Korean won (US$300) on treatment
Vaccines Covered	Government recommended vaccines and those listed in legislation	Compulsory and emergency vaccines	Government recommended vaccines
Filing deadline (years after)	Onset of nonfatal injury (3), fatal injury (2)	Onset (5), facts establishing a relationship (2)	Adverse event (5)

	United States of America	Taiwan	Republic of Korea
Standard of Proof	Vaccine injury table or by proving causation (80% of settlements are negotiated prior to a decision about causation)	Related or possibly related injury	Definite, probable, and possible causality is accepted
Types of Compensation	Medical (unreimbursed), lost wages, noneconomic losses, future care costs, death, attorney's fees	Medical, funeral, illness, disabilities, other events	Medical, funeral, illness, disabilities, other events
Litigation Rights	Yes, if settlement rejected, plus right of appeal	Yes, and has right of appeal	Yes, if settlement rejected, plus right of appeal
Legislations	「Public Health Service Act」 Part 2 - National Vaccine Injury Compensation Program	「Communicable Disease Control Act」 Paragraph 3, Article 70, Paragraph 5, Article 21 「Budget Act」	「Infectious Disease Control And Prevention Act」

* The Fund is a special fund under the Health Care Fund set by Subparagraph 2 of Paragraph 1 of Article 4 of the Budget Act

[16] Crum, T., Mooney, K., & Tiwari, B. R. (2021). Current situation of Vaccine Injury Compensation Program and a future perspective in light of covid-19 and emerging viral diseases. *F1000Research*, *10*. https://doi.org/10.12688/f1000research.51160.2

[17] Looker, C., & Kelly, H. (2011). No-fault compensation following adverse events attributed to vaccination: A review of International Programmes. *Bulletin of the World Health Organization*, *89*(5), 371–378. https://doi.org/10.2471/blt.10.081901

2.3.4. Findings

Despite the lack of available data on Taiwan's VICP, findings show that both Korea and Taiwan have a more lenient evidence threshold, which is in accordance with WHO guidelines. In Korea, compensation claims are allowed if the injuries are a) definitely related, b) probably related, or c) possibly related to a vaccine, and around 68 percent of vaccine compensation claims are approved. In Taiwan, there are three levels of causal relationship: an injury is related, an injury is possibly related, and an injury is unrelated. The first two categories of injuries are reimbursed, and 40 percent of claims were successful during 15 years. The Taiwanese system has a solid track record of settling claims in a timely manner, and it appears that the expert working group's persistent efforts are primarily responsible for expediting claim processing (Keane et al., 2019).

In contrast, it appears that the VICPs in Korea and Taiwan function under a looser standard of proof, which might loosen controls on the amount of compensation given out to successful claims. According to data presented by Kim et al. concerning the Korean program, compensation claims are allowed if the injuries are a) definitely related, b) probably related, or c) possibly related to a vaccine. The recompense claimed is wholly paid in all three categories. This implies that once an award satisfies one of the three pillars of the standard of proof, the amounts paid out to claimants are about the same.

The main differences between the three countries were in the administration and funding sources. The United States of America and Taiwan both relied on vaccine levies from manufacturers, whereas the Korean VICP relied mainly on the government treasuries. Additionally, Korean VICP has an eligibility requirement that limits individuals who spent less than 300,000 won on their injuries from filing compensation claims, which is indicative of the fact that Korean VICP is designed to compensate for serious injuries caused by immunization.

Furthermore, it appears that whatever the amount of money a claimant specifies in their compensation claim, if successful, the determined amount is paid to the claimant. In suggesting a similar relaxed application in Taiwan, Wang shows that the level of a causal

relationship is categorized into three types: an injury is related, an injury is possibly related, and an injury is unrelated. Applying a relaxed standard of proof allows the adjudicating panel to consider the merits of different levels of evidence, and the benefit of the doubt tends to be resolved in the claimant's favor (Keane et al., 2019).

The high level of legal representation hired and funded by the system in the United States is one of the significant contrasts between the VICP in the United States and those in the other jurisdictions we looked at in the literature. When compared to other jurisdictions, this element of the USA VICP adds considerably to greater overhead expenses. According to the information presented, attorney fees and expenses for pre-merit interim payments account for approximately one-fifth of total fees and costs in the program. Furthermore, the VICP does not limit the price of legal representation; regardless of whether a lawyer wins or loses, there are automatic legal fees, therefore there is no incentive to ever stop filing for claims within the VICP.

3 Application in the Context of COVID-19 and future pandemics

VICPs are increasingly relevant in the present global situation given the current coronavirus 2019 (COVID-19) pandemic and the need to rapidly establish public trust in immunization. The world has continually faced serious public health threats with several emerging and reemerging infectious diseases. Vaccination is already in progress worldwide, and as of December 23, 2021, over 8.6 billion vaccine doses have been administered (WHO, 2021).

3.1 United States of America CICP program

Like the United States, some jurisdictions have extended immunity against legal claims related to the manufacturing, testing, development, distribution, and administration of COVID-19 vaccines. Separately, the law provides for a publicly funded and administered program of compensation for those suffering severe side effects. The Public Readiness and Emergency Preparedness (PREP) Act was enacted on December 30, 2005[18]. The purpose of the act is to encourage companies to promptly release medical countermeasures during public health emergencies[19]. The PREP Act precludes liability for defects in diagnostics, therapeutics, and vaccines under both federal and state law for any loss, “caused by, arising out of, or resulting from” the application of a “covered

[18] *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, Pub. L. No. 2020-05484, 85 FR 15198 (2020).

[19] *The PREP Act and COVID-19*, Cong. Res. Serv., https://crsreports.congress.gov/product/pdf/LSB/LSB10443, at *1 (last visited Sep. 22, 2020).

countermeasure"[20]. PREP Act declarations have been made for H1N1, Ebola, botulism toxin, anthrax, smallpox, and acute radiation syndrome (Halabi, 2021).

CICP was created for the public to protect those who have been injured by vaccines, drugs, or diagnostic tools that may have been used in the emergency situations like COVID-19. Examples of covered countermeasures include vaccinations for 2009 H1N1, Pandemic Influenza (excluding seasonal influenza vaccines), Anti-virals, Anthrax, Smallpox, Botulinum Toxin, and other types of emergencies.

One must file a request for a benefits package. Upon submission, the request is reviewed by the CICP committee to determine the claimant's eligibility which is followed by determining the extent to which type and amount of compensation the claimant may receive. Requested compensation is denied if the request is found ineligible at any point in the committee review process. All claimants can rightfully request a reconsideration, in which case the review process will be convened by a qualified panel independent of the program. The program has a one-year filing policy which means the claimant need to file a claim before a year has gone by since the event an alleged countermeasure injury. It is known to grant compensation for only 8% of the claimants of CICP.

CICP's role was to remove the issue of liability in national emergencies It was first used in H1N1, but it is not limited to vaccines, ventilators, and drugs used for treatments. Since 2010 and until 2021 April, according to 11Alive, only 6% was approved out of 701 total claims. From June 2020 to April 2021, 255 claims were filed, and 210 were pending, 45 denied, and 0 approved cases[21]. In January 2021, the secretary of HHS changed the criteria of vaccine injury compensation by removing shoulder injuries from the

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[20] *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19,* Pub. L. No. 2020-05484, 85 FR 15198, 15200 (2020).

[21] *COVID-19 treatment and vaccine injury claims include everything from soreness to attempted murder*. Youtube. (2021, April 23). Retrieved December 6, 2021, from https://www.youtube.com/watch?v=olM3Bel11Rs.

program[22]. Another rule allows HHS to stop vaccines from automatically entering the compensation program which could have huge implications for COVID-19 vaccines. Current claims are handled by a lesser-used CICP which does not pay as much or give payouts as often.

According to Bloomberg law, many critics say that CICP is opaque and only offers payouts to very few individuals. Also, there were growing concerns among the legal community in the United States that Countermeasures Injury Compensation Program, a program that currently compensates for COVID-19 vaccines, is a failure due to an opaque review process that fosters public distrust, vague vaccine injury table and causality criteria, and mounting vaccine injury claims without any recourse from the government (Lee and Lopez, 2021). If other countries were to benchmark CICP, they need to address lack of transparency by clarifying how each review process is done, how each decision is made, and communicating effectively by utilizing positive media representation.

[22] *HHS Secretary Makes It Harder to Get Compensation for Vaccine Injuries*. Youtube. (2021, January 27). Retrieved December 6, 2021, from https://www.youtube.com/watch?v=P92cZSiMmo8.

Table 8. Comparison of COVID-19 Vaccine Compensation Programs[23]

	United States of America	Taiwan	Republic of Korea
Legislation	「Public Health Service Act」 Part 2 -National Vaccine Injury Compensation Program	Prevention and Treatment of Infectious Diseases Article 30, Paragraph 4	「Infectious Disease Control And Prevention Act」 Article 71 (Compensation by the State for Injury Caused by Vaccination)
Administration and Funding	Countermeasures Injury Compensation Program (CICP) Fund	Manufacturers, Importers, Donations, Interests generated on the VICP Fund	Government
Process and Decision Making	Department of Health and Human Services, Health Resources & Services Administration (HRSA)	Committee for the Management of Health Care Fund	Korea Disease Control and Prevention Agency (KDCA)
Filing deadline (years after)	Onset of nonfatal injury (3), fatal injury (2)	Onset (5), facts establishing a relationship (2)	Adverse event (5)
Elements of Compensation	Medical (unreimbursed – no upper limit), lost wages (max. US$50,000/yr), noneconomic losses, future care costs, death (max. US$50,000/yr), attorney's fees	(Related) Injury or death (max. NT$6,000,000 lumpsum – approx.US$215,000) (Possibly related) Injury or death (max. NT$3,500,000 lumpsum)	(approx. US$400,000 lumpsum) Additional: Funeral costs, Unreimbursed medical costs, Disability (lumpsum) costs
Litigation Rights	Yes, if settlement rejected, plus right of appeal	Yes, and has right of appeal	Yes, if settlement rejected, plus right of appeal

[23] World Laws Information Center. (2021, September 16). *COVID-19 Vaccine Injury Compensation Programs of the World*. World Laws Information Center. Retrieved October 19, 2021, from https://world.moleg.go.kr/web/dta/lgslTrendReadPage.do?CTS_SEQ=49649&AST_SEQ=3891&ETC=1#.

4 Findings and Recommendations

4.1 The Need for a Change in Source of Funding

The funding source for vaccine-injury compensation programs is primarily a reflection as to which entity has decision-making power. The South Korean government uses national treasuries to fund its vaccine injury compensation program. In many countries, compensation programs are a secondary source of funding for medical and disability expenditures (Looker and Kelly, 2011), meaning that claimants are often covered first by national public or private insurance. As a result, the compensation schemes might be small in scale and do not have to cover all expenditures that could be assessed in a tort or product liability case.

In this study, the results show that the U.S. and Taiwan operate their VICPs by mandating a vaccine levy from manufacturers per dosage sold. However, South Korea operates through a national treasury which could potentially be a burden to the national budget in the long run. Therefore, the Korean government should benchmark year-round CICP fund to expand vaccine tax policy to not only non-NIP vaccines but to NIP vaccines, and to also to secure enough funding to cover fast-track vaccines or to halt outbreaks during future pandemics to secure more funding for the vaccine injury compensations. This year-round fund does not have to be limited to compensation payouts only; it can be used to provide funding for research on vaccine-related adverse events and be used for administration expenses.

4.2 The Need for a More Inclusive Vaccine Injury Table

The governmental authority operates the program, and the fund is from Treasury in Korea. The characteristics of VICPs in other countries should be carefully taken into account for the improvement of KNVICP. In Korea, a lawsuit is still available even KNVICP had decided that the injury or unwanted event would not be compensable. However, the suit usually takes longer and easily tires individuals involved in the process than the compensation program. In Korea, the VICP is limited to paying compensation for injuries connected to a list of vaccinations authorized by Korean authorities, but in Taiwan, the VICP is supported by a premium paid by vaccine producers or importers once bought vaccines have been approved and certified. In Taiwan, the VICP offers financing for claims reimbursement, operational expenses, and research into adverse inoculation reactions.

Vaccine and vaccination-related adverse event allegations must be handled quickly and efficiently. Failure to do so could damage the public's trust in vaccines and have serious ramifications like low vaccination coverage, even after science proves that the adverse event was not caused by the vaccine (e.g. autism and MMR). More than 70 vaccine products with various combinations of components are now being used in Korea, and many newly developed vaccines are also being licensed and introduced to the public (Jo and Kim, 2013). There is a need for a clear understanding and distinction between vaccines and their known adverse events. There's also a need for programs and legislatures to include fast-track vaccines for disease X and cover injured individuals. Accordingly, the study findings of Jo and Kim suggest amendment of the table, such as a specification of each vaccine with injuries and with specific time criteria, should be made (2013).

4.3 The Need for a More Effective Review Process

In the United States, a country with 334 million in population, only eight special masters evaluate vaccine injury claims. In Taiwan, a country with 23.8 million in population, 19 to 25 part-time VICPWG members review vaccine injury claims. In South Korea, a country with 51.2 million in population, 15 to 25 members in the KACVIC. KACVIC reviews vaccine injury claims quarterly, but with Covid-19, the review committee has been meeting bi-monthly to expedite the compensation process. In numbers, one special master per 41.7 million Americans, one expert reviewer per 2 million Taiwanese, and one expert reviewer per 2 million Koreans. If VICPs were to meet up to the expectations of original purposes, there need to be more reviewers or more frequent review meetings in order to process a larger number of vaccine injury claims in a timely and more effective manner.

5 Discussions and Conclusion

5.1 Limitations

A Problem in comparative research is that what appears to be the same category in various nations may be defined differently. Definitions open to interpretation and words lost in translations are some of the limitations of this study. There is also a possibility for more suitable countries to compare with KNVICP for the purpose of strengthening South Korean VICP.

Also, the variety of data sources I used in this study made a uniform assessment of their quality difficult. The majority of the materials were not traditional research papers; instead, they were discussion documents that attempted to explain the benefits and drawbacks of various schemes. These resources draw on a mix of sources, including legal and policy papers, grey literature on the schemes in question, and secondary descriptive summaries of administrative data on the schemes. Data on Taiwan was scarce since it was seldom available in English, and research publications did not correctly distinguish between Taiwanese and Chinese policy.

5.2 Discussions

The majority of vaccinations given in the United States are covered under the VICP. This no-fault program was established to give an alternative channel for ensuring prompt and reasonable compensation for vaccine injuries, as well as to shield vaccine producers from liability in order to promote them to continue developing vaccines. In many circumstances, claimants who acquire recognized symptoms within a particular time frame following vaccination may not need to establish that the vaccine caused their injuries, leaving just the amount of damages in dispute. The CICP, on the other hand, is far less generous and less accessible than the VICP. It compensates victims only for the most severe injuries, has a greater burden of evidence than the VICP, has a one-year statute of limitations following the date of vaccination, and caps damages awarded. The CICP, for example, caps lost-income recovery to $50,000 per year of unemployment and excludes compensation for pain, suffering, or mental distress (Van Tassel, Shachar and Hoffman, 2021). If the Korean government were to benchmark CICP to put in place a fund that operates year-round, they must seek ways to address the lack of transparency that lies in CICP and to specify the causal association between adverse reactions and vaccinations.

According to a study on the costs of vaccine injury claims, the United States has paid out approximately US$4.43 for 7,575 vaccine injuries from 1989 throughout 2020 (Paull, 2020). This was US$585,012 per claimant, and of the total claims filed, only 34% were successful, and the rest were dismissed or not progressed. It is estimated that the Covid-19 vaccine roll-out in the US alone would cause US$813 million of vaccine injuries at the least and vaccinating the world's population with two-dose Covid-19 vaccine may cause US$12.7 billion of vaccine injuries (Paull, 2020). This study shows that more injury claims will mount to be a financial burden for many countries and that the need for stable compensation fund is increasing.

5.3 Conclusion

Injuries caused by vaccines are unpredictable and unavoidable. The VICP was created by the government to acknowledge that individuals may suffer from vaccine-related injuries as a result of their compliance with the national vaccination program. The program achieves the original legislative goals by compensating persons who may have been injured due to vaccination. The no-fault basis of VICP addresses the limitations of our litigation system that require demonstration of either negligence or liability for the alleged casualties of vaccines.

The compensation includes various subsidies and focuses on giving financial assistance to those who have been injured and their families. Other benefits of VICP are that the program motivates vaccine innovation and production because it relieves the financial burden of the claims filed by individuals allegedly injured by vaccine-related adverse events. Relatedly, VICPs help individuals to claim legal justice since litigations can be quite costly, and compensations are no guaranteed outcomes. Compensation systems also lead to a more effective and inclusive vaccination program overall. Finally, VICPs can provide healthcare personnel and the general public the assurance that individuals who are potentially injured following vaccination will be supported.

However, the program should establish a Compensation Fund that operates year-round to reduce the burden on the government during national emergencies, place definitive criteria on the vaccine injury table to include additional vaccines and recently identified adverse events and require continuous and more frequent attention for the compensation claims to make the program decisions more transparent, more convincing in fulfilling its original purpose.

Determining the criteria starting the eligible period to file a claim is complex and we still need more research on identifying causality and correlation of symptoms to COVID-19 vaccines is needed. Until then, transparent and accurate risk communication

policies should carefully address the issue as to not mislead the public into believing that specific medical symptoms are directly associated with certain vaccines.

I believe that immunization governance, as a whole (i.e., public health legislation, immunization legislation/policies, actor regulation (e.g., physician, pharmacist), national procurement practices, and so on) should be explored, along with the broader public and global health (and health justice) systems, in order to identify local, national, and international individual and systemic barriers and bottlenecks that undermine the efficacy of vaccination programs. Further studies on vaccine injuries and financing of compensation programs is needed along with the establishments of legislation for a more comprehensive compensation process.

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= ABSTRACT IN KOREAN=

우리나라 예방접종 피해보상제도 개선방안:
-미국·대만과의 비교제도론적 고찰을 중심으로-

현재 코로나 19 백신의 안전성에 대한 국민의 불신이 커지고 있다. 방역패스 정책에도 불구하고 미디어에서는 드물게 발생하는 백신 부작용에 대해 보도를 하며 국민 불신에 불을 지피고 있다. 현재까지도 예방접종을 기피하는 이들도 아직 많이 존재하며 이들은 공중보건에 심각한 문제를 초래할 수 있기 때문에 예방접종 피해보상제도에 대한 연구를 통해 보상신청에 대한 이해를 증진시키고자 한다.

본 연구에서는 비교법제도론적 질적연구를 시행하며, 최대 유사 체계 설계 디자인에 근거하여 미국, 대만, 한국의 예방접종 피해보상제도를 살펴보고 우리나라의 현 제도에 대한 개선방안을 찾고자 하였다. 또한 각국의 피해보상제도를 통해 코로나19 팬데믹 상황속에서 코로나19 백신에 대한 보상은 어떻게 이루어지고 있는지 알아보고 미래 감염병에 대응할 수 있는 체계 설립에 대한 제안을 하고자 한다.

미국 및 대만의 피해보상제도와 다르게 한국에서는 특별예산을 편성하여 피해보상을 시행하고 있다는 점을 찾았다. 이는 팬데믹으로 인해 증가하고 있는 코로나19 예방접종 피해보상 신청건수에 대한 대응을 하기 위해 상시 운영되는 예산의 필요성이 더욱 부각되는 결과였다. 또한 전세계적으로 인과성 인정에 대한 기준표가 다 상이하며, 백신 피해 기준표 (Vaccine Injury Table)에 백신이 포함되기 위해서는 정부의 승인 등 오랜 시간을 거쳐야하기

때문에 구체적이고 최신의 백신 부작용 사례들을 반영한 국내 예방접종 피해 기준표를 만들어야 하는 필요성이 대두되었다. 또한 인구대비 피해보상 전문위원회의 심의 횟수와 전문인력의 부족한 것으로 드러났다.

따라서 해당 제한점을 개선하기 위해 한국 정부는 상시 운영하는 예방접종 피해보상 펀드를 구축하는 것을 후속 연구를 통해 고려해야 한다. 또한 백신 피해 기준표를 최신의 정보를 근거로 구체화하여 더 많은 백신을 포함시켜 적절한 보상이 이루어지게 해야 하며, 전문위원회 심의 횟수와 전문인력의 확보를 통해 제도의 효율성을 극대화해야 한다.