

# CLINICAL AND EXPERIMENTAL VACCINE RESEARCH

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## Perspectives on vaccine injury compensation program in Korea: the pediatricians' view

**Purpose:** Since National Immunization Program (NIP) was implemented recently in Korea, public attention on vaccine safety is increasing. This study was aimed to investigate perceptions of pediatricians on the vaccine injury compensation program and to acquire their suggestions to improve the program.

**Materials and Methods:** Pediatricians working in primary care were surveyed at the sites of the annual Korean Pediatric Society meeting or its regular regional branch meetings during September and October 2012. A questionnaire consisted of 15 items about the Korean National Vaccine Injury Compensation Program (KNVICP) was distributed and collected directly from the pediatricians.

**Results:** A total of 340 responses were collected. While only 16% of responded pediatricians answered they knew the program well, 11% answered they did not. Twenty-six percent answered a need to expand the types of vaccines and its injuries. Most responders (82%) wished the compensation program to cover the injuries of non-NIP vaccines. On the filing procedures for compensation, they preferred reducing the minimum medical cost limit to claim (94%).

**Conclusion:** On the basis of this survey, it is suggested to provide more active informative education on KNVICP to primary care pediatricians and to improve the program considering the pediatricians' opinions.

**Keywords:** Pediatrics, Data collection, Vaccines

### Introduction

There is no doubt that vaccine is one of the most effective and important measures to control infectious diseases in public health [1]. However, for the fundamental mechanism how a vaccine is working is a mock infection of a pathogen, presuming adverse event following immunization (AEFI) is not difficult, while the AEFI may be expectable or unexpected, and minimal or severe, even lethal [2,3]. Besides, usually, a vaccine is a biological substance administered to large, healthy population to prevent diseases, a small safety issue may have great impact on overall vaccine coverage rate and its final effectiveness. Therefore, vaccine safety is being more spotlighted in the public as National Immunization Program (NIP) has been launched recently in Korea [4].

Obtaining confidence not only of vaccinees, parents, and guardians, but also of primary care pediatricians in vaccine safety is crucial to operate successful public vaccine program, for the physicians who care children and adolescents are in the forefront of

the field. However, there has been no study on the attitude or perspectives of vaccine providers on the vaccine safety management system in Korea.

Since established in 1994, Korea National Vaccine Injury Compensation Program (KNVICP) has been an important and essential measure to assure both public and healthcare providers on the vaccine safety [4,5]. After 16 years experience of the program, this study was performed to see how pediatricians recognize the KNVICP and to hear any suggestions to improve the program.

## Materials and Methods

### Study setting and population

During September and October 2012, a survey was performed to randomly selected primary care pediatricians distributed nationwide in Korea who attended annual Korean Pediatric Society meeting or its regular regional branch meetings. At the time the survey was carried on, about 3,500 pediatricians were working in primary care, and the total number of board-certified pediatricians was around 5,800. A brief introduction was provided before the meetings or intermissions, and questionnaires were administered to the pediatricians and collected directly. For vaccine injuries covered by KNVICP refers to the table of AEFI and its time criteria (Table 1) [6], it was also presented.

### Survey design

The questionnaire was composed of 15 items which were categorized into 3 sections: each section regarded the perception of vaccine injury compensation program, opinions on the appropriateness of vaccine injury reporting system for compensation, and suggestions for the improvement of the program. It was developed in collaboration with Korea Centers for Disease Control and Prevention (KCDC). Questionnaire did not ask the characteristics of each responder.

## Results

### Perception of vaccine injury compensation program

Questionnaires from a total of 340 pediatricians were collected; i.e., about 10% of total primary care pediatricians in Korea were participated in this survey. Of them, 89% answered they knew well or roughly knew the KNVICP, while 11% answered they did not know the program.

**Table 1.** Reportable adverse events following immunization and its time criteria defined in the Communicable Disease Control Act in Korea

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
MMR	Other adverse events suspected as related with immunization	No limit
	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
BCG	Other adverse events suspected as related with immunization	No limit
	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

Adverse events of inactivated polio vaccine, hepatitis B vaccine, varicella vaccine, influenza vaccine, typhoid vaccine should be referred to the criteria for DTaP. DTaP, diphtheria and tetanus toxoids and acellular pertussis vaccine; Tdap, tetanus and diphtheria toxoids and acellular pertussis vaccine-adolescent and adult preparation; Td, tetanus and diphtheria toxoids-adolescent and adult preparation; MMR, mumps, measles, and rubella; BCG, bacille Calmet-Guerin.

### Opinions on the guidelines for the reporting of AEFI

#### *Variety of adverse events and vaccines to report*

Slightly over a half of the responders agreed to maintain the types of adverse events to be reported. However, 26% acknowledged a need to expand the types of vaccine injuries such as severe pain, skin rash, and complications associated with fever. They also suggested the reportable vaccines should not be limited to the vaccines listed in the reportable AEFI table.

#### *Time interval after administration*

Sixty-two percent of responders agreed with the time criteria of the injury table. Fourteen percent answered some modification on the criteria such as lengthening the time for neurologic sequelae in case of delayed recognition. Some answers indicated longer interval might cause difficulty in differential diagnosis.

*Report criteria for inactivated polio vaccine, hepatitis B vaccine, varicella vaccine, influenza vaccine, and typhoid vaccine*

Fifty-three percent of responders agreed with the present criteria, i.e., criteria for diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). However, 31% said adverse events of each vaccine should be described in detail.

#### **Opinions on compensation for percutaneous bacille Calmet-Guerin (BCG) vaccine and live attenuated Japanese encephalitis vaccine**

While intradermal BCG vaccine and inactivated Japanese encephalitis vaccine are included in NIP, percutaneous BCG vaccine and live attenuated Japanese encephalitis vaccine are non-NIP vaccines, but approved by Korea Food and Drug Administration and administered actively in Korea. We asked the pediatricians' opinion on the need for compensation for the injuries after these two vaccines. Eighty-two percent favored the inclusion of percutaneous BCG vaccine, while 10% disagreed. In addition, 78% positively answered for live attenuated Japanese encephalitis vaccine.

#### **Opinions on filing objection after decision of Korea Advisory Committee on Vaccine Injury Compensation**

With or without new reasons, only a single filing objection is allowed in the present KNVICP. We asked the pediatricians if it is appropriate, and 59% answered filing objection should be allowed only when a new reason was identified, while 35% said no need for amendment.

#### **Opinions on mandatory autopsy**

Seventy-one percent responded the need of mandatory autopsy in lethal cases while 25% answered that the autopsy should be done under legal guardian's will.

#### **Opinions on eligible period to file a claim**

According to the present Korean law, a claim must be filed within 5 years after occurrence of AEFI. However, the patients and/or parents might neither realize the initial symptoms nor remember the day of adverse events beginning. On this matter, 47% answered the criteria should start on the day when adverse events started, and 40% answered the day of diagnosis. For the appropriate duration of filing period, 61% answered within 5 years, same as at present while 14% answered within 3 years, 13% no limit, and 10% within 10 years.

#### **Number of times to requesting compensation payment**

At present, compensation money can be requested 4 times when adverse event becomes chronic. Forty-four percent responders accepted present system, while 33% suggested it might be paid once and 21% answered need of amendment such as increasing times of requesting.

#### **Minimal amount of injury treatment money to request compensation**

To be requested, the personal burden of medical treatment money should be KRW300,000 (about US\$300) or more. Ninety-four percent answered the minimum should be lowered, but 6% suggested that the minimum would be KRW500,000.

#### **Compensation for the money caused by disability before the disability is finally diagnosed**

At least 2 years are required to confirm the disability due to vaccine. However, the current rule does not allow the cost of braces, prosthetics, or assistances are compensated before the 2 years of preliminary period. On this matter, 75% answered these auxiliary cost should also be compensated even it was paid before the diagnosis was confirmed. Others took the present rules (16%), or answered they didn't know (9%).

## **Discussion**

Safety issue is one of the major obstacles to successful massive immunization practices [4,5,7-9]. For NIP is mainly for children and adolescents, primary care pediatricians are usually responsible for reporting AEFI when they notice the suspected case. Therefore, it is important for pediatricians to be familiar with laws and acts on vaccine safety management system, such as AEFI management system and vaccine injury compensation program. In this study, we found only 16% of pediatricians who participated in our survey answered that they knew well about KNVICP. Moreover, to the question asking about time criteria of AEFI, 22% selected the answer saying that they did not know at all. These findings suggest more active informative education on vaccine safety management is needed as an essential part of NIP.

In Korea, at present, many non-NIP vaccine products are having been licensed and administered to prevent the same infectious diseases that NIP covers [10]. These non-NIP vaccines, such as transcutaneous BCG vaccine and live attenuated Japanese encephalitis vaccine, are not included in NIP, for their cost-benefit is not superior than that of NIP vaccines or

they are not accepted as standards by authority. However, most primary care pediatricians answered these non-NIP vaccines should be guaranteed by KNVICP, for the vaccines cover same diseases as NIP vaccines do. Internationally, how the compensation program is administered and where the fund comes from are different from country to country: national/state government vs. pharmaceutical manufacturers, Treasury vs. tax on vaccine distribution. The governmental authority operates the program and the fund is from Treasury in Korea. This issue should be carefully taken into account for the KNVICP improvement, because these are used more popularly in private sector, and the private pediatricians are key vaccine providers in NIP.

Generally in our study, pediatricians showed consensus on expanding the variety of injuries/sequelae and lowering hurdle to file the claims. In Korea, a law suit is still available even KNVICP had decided the injury or unwanted event is not to be compensable. However, the suit usually takes longer and easily tires a no-fault-physician than the compensation program. This may explain why pediatricians prefer the program as a safety gear.

Determining the criteria starting eligible period to file a claim is a complex. It is hard to decide when the symptoms really started, because it is uncertain and vague to tell when vaccinees or their guardians realize the symptoms. As 40% of responders answered in our study, it could be an objective approach to decide on the criteria to be the point when a medical diagnosis is made. Acquiring a solid scientific evidence is basic to justify if the unwanted event is related to the immunization or not, especially in a lethal case. Nonetheless, for Korea tradition, culture, and laws, the autopsy is not mandatory, and a consent should be obtained from legal guardians to perform an autopsy. The authors agree with the 40% of the responders on that autopsy should be performed to find the causality and to accumulate the data on deadly adverse events.

Reportable AEFI table and vaccine injury table for compensation are a little different among countries. The table of KNVICP in effect today was established more than 15 years ago and is not in detail, while those of other countries are [9,11]. Now in Korea, more than 70 vaccine products with various combinations of components are used, and many newly developed vaccines are also being licensed and introduced to the public. Accordingly, we suggest amendment of the table, such as specification of each vaccine with injuries and with specific time criteria, should be made.

This study has limitations. The responders were all pediatricians, but physicians with other specialty also take parts in NIP. We did not asked the characteristics of each responder, such as age, sex, how long they had been working with pediatric specialty, or in which province they were working. So, we could not see any possible bias related with their characteristics on selecting the answers.

In conclusion, we could see in this survey that pediatricians should be aware vaccine injury compensation program and its importance. In addition, we suggest that amendments of the program could be made in consideration of the opinions of pediatricians, the front-line vaccine providers.

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