Adverse Event Following Immunization Monitoring System in Japan

Mai Okuyama, MD, PhD,* Hajime Kamiya[®], MD, MPH, PhD,* Satoshi Kamidani, MD, PhD,† and Akihiko Saitoh, MD, PhD‡

Abstract: Although immunization is essential for maintaining public health, adverse events following immunization (AEFI) occur at a certain rate. Therefore, it is extremely important to conduct postimmunization safety monitoring and relief systems to ensure the safe implementation of immunizations for the public. This article summarizes the monitoring system of AEFI and the unique compensation system (so-called relief system) in Japan. In addition, current problems and issues on the AEFI monitoring and relief system will be specified, and immunization-related systems planned to be built in the future in Japan will be introduced.

Key Words: safety monitoring, adverse event following immunization, the relief system, Japan

(Pediatr Infect Dis J 2024;43:e52-e56)

THE MONITORING SYSTEM OF ADVERSE EVENTS FOLLOWING IMMUNIZATION IN JAPAN

Monitoring the safety of immunization is essential for the national immunization program. In Japan, there are 2 data sources for monitoring immunization safety. The first is individual case safety reports (ICSRs) from the healthcare professionals of the medical institutions, and the other is ICSRs from marketing authorization holders (MAHs) (Fig. 1). It was established in 2013 that if a physician suspects adverse events following immunization (AEFI), they are obligated to report the event to the Ministry of Health, Labour and Welfare (MHLW) in accordance with the Immunization Act. Meanwhile, ICSRs from MAHs are regulated based on the Act on Securing Quality, Efficacy, and Safety of Products, including Pharmaceuticals and Medical Devices.

The reporting criteria for physicians to report AEFI are in Article 5 in the Order of MHLW (Table 1). It defines the reporting criteria of symptoms to be reported in each vaccine if they are observed during a specified period after which the vaccine is administered, regardless of a clear causal relationship. In addition, even if the defined duration and symptoms are not met for

Accepted for publication October 30, 2023

From the *Center for Surveillance, Immunization, and Epidemiologic Research, National Institute of Infectious Diseases, Tokyo, Japan; †Department of Pediatrics, The Center for Childhood Infections and Vaccines of Children's Healthcare of Atlanta, Emory University School of Medicine, Atlanta, Georgia; and †Department of Pediatrics, Niigata University Graduate School of Medical and Dental Sciences, Niigata, Japan.

Supported by the Ministry of Health, Labour, and Welfare Program, Grant No JPMH21HA1004.

S.K.'s institution has received funding from SK and reports research support to his institution from Pfizer, Emergent BioSolutions, Meissa, CDC, and NIH. Dr. A.S. has received honoraria from MSD, Pfizer, Moderna, Tanabe-Mitsubishi Pharmaceuticals, and Biken Co. Ltd. for lectures. Other authors have no conflicts of interest to disclose.

Address for correspondence: Hajime Kamiya, MD, PhD, MPH, Center for Surveillance, Immunization and Epidemiologic Research, National Institute of Infectious Diseases, Toyama 1-23-1, Shinjuku-ku, Tokyo. 162-8640, Japan. E-mail: hakamiya@niid.go.jp

Copyright © 2023 Wolters Kluwer Health, Inc. All rights reserved.

ISSN: 0891-3668/24/432-e52e56 DOI: 10.1097/INF.0000000000004184 THE RELIEF SYSTEM FOR INJURY TO HEALTH WITH
VACCINATION IN JAPAN

Overview

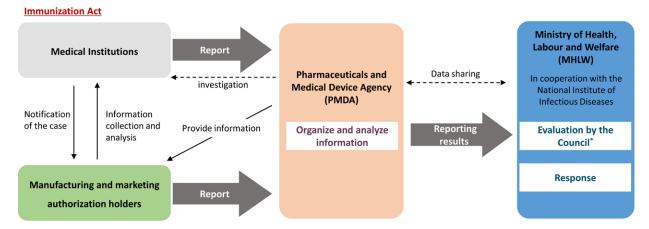
The unique compensation system (so-called Relief System) for injury to health with vaccination in Japan is based on the no-fault compensation scheme stipulated in Article 15 of the Immunization Act of 1976.⁵ This system is independent of the aforementioned monitoring system of AEFI.

The person who has suffered after the immunization or their family/guardian can request relief from the municipality in which the certificate of residence was registered at the time of vaccination. The external experts at the municipality investigate the case

each vaccine, a physician may report a case that requires hospitalization, has residual complications or results in death if they think it might be associated with vaccination. Table 2 lists the items of information collected in the report of AEFI. If the event to be reported is diagnosed as acute disseminated encephalomyelitis (ADEM), Guillain-Barré syndrome (GBS), thrombosis including thromboembolism but limited to those with thrombocytopenia (TTS), myocarditis and pericarditis, the respective survey forms¹ have to be submitted to evaluate the diagnosis by using the Brighton Classification² if available. On the other hand, the report from MAHs does not define when and what symptoms are to be reported. In addition, there is another path whereby the vaccinated person or the family reports the symptoms after immunization to the municipality, which is reported to the MHLW through the prefecture government.

The ICSRs from the healthcare professionals and MAHs are submitted to the Pharmaceuticals and Medical Devices Agency (PMDA). PMDA and external experts organize and analyze the ICSRs and evaluate the causal relationship between the vaccine and the symptoms. The documents are submitted to the joint council, and the council discusses whether there are any serious concerns that require immediate action such as suspension of vaccination³ (Fig. 1). The joint council consists of an adverse reaction review subcommittee positioned under the Health Science Council for Immunization and the Pharmaceutical Affairs and Food Sanitation Council, held usually every 3 months.

In addition, a health status survey monitors relatively frequent symptoms (fever, swelling of immunization site, seizure, vomiting, diarrhea, cough/runny nose, etc.) for a certain period after routine immunization. Managed by MHLW, physicians distribute questionnaires to vaccinated persons or their guardians, and they are asked to observe and record their health status from the date of vaccination. The observation period is 28 days (4 months for the BCG vaccine), and reporting is requested even if no adverse reactions are observed. Results are analyzed annually and evaluated by the Joint Council. This relatively small cohort survey system was launched to inform the public about common adverse effects and ensure safe immunization practices and it was also utilized when the COVID-19 vaccine was introduced.



Act on Securing Quality, Efficacy and Safety of Products **Including Pharmaceuticals and Medical Device**

*Joint council (Health Sciences Council and the Pharmaceutical Affairs and Food Sanitation Council)

FIGURE 1. Evaluation structure for vaccine safety monitoring.

and submit the application form to the prefecture government, and the prefecture government checks the contents and submits it to the MHLW. At the MHLW, the causal relationship is examined by the Examination Committee for Certification of Sickness and Disability. The committee thoroughly reviews each case, considering both medical and legal perspectives, to ensure the symptoms are medically plausible and temporally related, with no other evident cause. This review is guided by the principle that certification does not necessitate a strict medical causal relationship. Still, it covers cases where it is undeniable that immunization has led to the symptoms. Based on the examination results, the applicant will be notified whether the municipality will provide the compensation (Figure 2). Between February 1977 and December 2021, 3,522 cases were certified by MHLW for routine vaccines other than the COVID-19 vaccine. 7,8 In 2018, 46% of certified cases were approved as undeniably attributable to immunizations.9

BENEFIT TYPE AND AMOUNT

The types of benefits for the relief system for AEFI include medical expenses, medical allowance, pensions for rearing children with disabilities, disability pensions, lump-sum benefits for death, survivors' pensions, lump-sum benefits for survivors, funeral expenses, and additional amounts for nursing care.6 However, the amount of money paid as relief depends on the category to which the administered vaccine belongs. The Immunization Act categorizes routine vaccines into 2 categories (A and B) based on the purpose of the vaccine. 10 Diseases included in category A are diphtheria, pertussis, tetanus, poliomyelitis, hepatitis B, hemophilus influenza type B, pneumococcal (PCV13), tuberculosis (BCG), measles, rubella, varicella, Japanese encephalitis, human papillomavirus and rotavirus, and category B is seasonal influenza and pneumococcal (PPSV23) for older people or those with underlying medical conditions. The vaccine in category A is vaccinated to prevent the outbreak and spread of the disease because the disease is contagious and can cause severe outcomes. Therefore, category A vaccines are strongly recommended to prevent the disease in the majority of the population acquiring immunity. Routine immunization for children is classified as category A. On the other hand, vaccines in category B can prevent disease onset or its severity in individuals. The amount of relief differs between categories A and B, but the amount is higher for category A. For example, as of June 2023, if a disability pension (Class 1) is approved, 5,175,600 yen (about \$40,000) per year is paid for category A and 2,875,200 yen (approximately \$22,000) for category B annually. If the death due to illness caused by vaccination is approved, lump-sum benefit for death of 45,300,000 yen (approximately \$350,000) is paid in category A. In category B, survivors' pensions of 2,514,000 yen (approximately \$19,000) annually (limited to 10 years maximum) are paid if the person died was the financial provider for the bereaved, and 7,542,000 yen (approximately \$58,000) are lumpsum benefits for survivors are paid if the person died was not the financial provider for the bereaver. The relief system for voluntary vaccines other than routine vaccines is provided by the Relief System for adverse reactions to drugs which is stipulated in the Act of PMDA, Independent Administrative Agency.¹¹ The benefit amount for category B is set with reference to the benefit amount of adverse reactions to drugs.

FUTURE PROSPECTS OF SAFETY ASSESSMENT OF **IMMUNIZATION IN JAPAN**

The current monitoring system of AEFI in Japan is a passive reporting system similar to the United States. Vaccine Adverse Event Reporting System, which is useful for the early detection of adverse reaction cases and accumulating unusual events. However, data on individuals without AEFI is not reported, and denominator information is not available, making it challenging to determine the causal link between immunization and adverse events and estimate the incidence of the events by doses given. In addition, the systematical challenge exists, such as immunization history and medical records are stored separately by municipalities and medical institutions, and no readily accessible immunization registry is available. Under such a system, there was concern that people's confidence in the safety assessment of vaccines could be reduced. Therefore, the MHLW revised The Immunization Act in 2022, which includes plans to establish a nationwide digital immunization registry. It is stated that the future goal is to connect immunization-related information, including immunization registers, a national database of health insurance claims and ICRS, to establish a database that will allow us to better assess the causal relationship between vaccination and adverse reactions than the current system. We expect that this change will lead to more robust safety monitoring and assessments.

 TABLE 1.
 Reporting Criteria for Suspected Adverse Event Following Immunization under the Japanese Immunization Act

hours S days Hours Hours Hours S days	DipAthbering 2 Locapholatistic encephalogathy 4 hours DipAthbering 2 Exercipabilitis dencephalogathy 7 days Polito myelitis 4 Dente and a comparation of encephalogathy 7 days Anaphylaxis 4 Hours 2 days Rubella 2 Acute disseminated encephalogathy 22 days Statuchalitis/Encephalogathy 22 days 24 days Anaphylaxis 4 hours 4 hours Others 2 Acute disseminated encephalogathy 22 days Anaphylaxis 2 Acute disseminated party 2 days Anaphylaxis 4 hours 4 hours Tuberculosis (BCC) 1 Assimute distingencephalogathy 2 days Anaphylaxis 4 hours 4 hours BCG odhers 3 Exceeding (setemyellis/periotitis) 4 hours Anaphylaxis 4 hours 4 hours Anaphylaxis <th< th=""><th></th><th>Disease</th><th>Symptom</th><th>Period to Onset</th><th>Symptoms</th></th<>		Disease	Symptom	Period to Onset	Symptoms
A	Annaholyaxis 1 1 2 2 2 2 2 2 2 2	Reporting criteria	Diphtheria Portnesis	1 Anaphylaxis 9 Encaphylitis(ancaphylomethy	4 hours	If "others" is selected on the left
Others	5 Others 5 Others 2 Stays			3 Seizure	7 days	a Apnea
Anaphylaxis	Annaphylaxis Annaphylaxis Annaphylaxis Annaphylaxis Annaphylaxis Annaphylaxis Annaphylaxis Annaphylaxis Annaphylaxis Brocephalitis/Brocephalopethy 28 days 2 Antaphylaxis 2 Andaphylaxis 2 Andaphylaxis 2 Andaphylaxis 2 Andaphylaxis 2 Andaphylaxis 3 Encephalitis/encephalopethy 28 days 4 Encephalitis/encephalitis/encephalopethy 28 days 4 Encephalitis/enc			4 Thrombocytopenic purpura	28 days	b Bronchospasm $_{c}$ and $_{d}$
2 Acuté disseminated encephalomyelitis (ADEM) 28 days	2 Acuté disseminated encephalomyelitis (ADEM) 28 days			5 Others 1 Ananhylavis	- 4 hours	d Multiple sclerosis
State	State			2 Acute disseminated encephalomyelitis (ADEM)	28 days	e Encephalitis/encephalopathy
Thrombocytopenic purpura 28 days	Thrombocytopenic purpura 28 days			3 Encephantis/Encephalopathy 4 Seizure	28 days 21 days	g Seizure
Anaphylaxis	Anaphylaxis			5 Thrombocytopenic purpura	28 days	h Guillain-Barré syndrome
ADEM	ADEM			6 Others	7	i Facial nerve nalsv
5 Encephalitis/encephalopathy 28 days 5 Chters 7 days 6 Others 28 days 1 Anaphylaxis 4 hours 2 Disseminated BCG infection 1 years 2 Disseminated BCG infection 2 years 4 Skin thereutosis-like lesions 3 months 5 Pyogenic lymphachitise lesions 4 months 6 Meningitis (only caused by BCG) - 7 Others - 1 Anaphylaxis 4 hours 2 Seizure 7 days 3 Thrombocytopenic purpura 4 hours 2 ADEM 28 days 3 Guillain-Barré syndrome 28 days 4 Thrombocytopenic purpura 28 days 5 Vasovagal reaction (accompanied by syncope) 30 minutes 6 Various Symptoms, mainly pain or movement disorders - 7 Others - 1 Anaphylaxis 2 days 2 ADEM - 3 Asaptic meningitis (accompanied by herpes zoster) - 1 Anaphylaxis 2 days 2 ADEM - 3 Anlitiple selerosis 2 days <td> Encephalitis/encephalopathy</td> <td></td> <td></td> <td>1 Anapnylaxis 2 ADEM</td> <td>4 nours</td> <td>k Peripheral nerve palsy</td>	Encephalitis/encephalopathy			1 Anapnylaxis 2 ADEM	4 nours	k Peripheral nerve palsy
4 Seizure 7 days 6 Others 8 days 6 Others 4 hours 2 Disseminated BCG infection 1 year 2 Disseminated BCG infections 2 years 3 Disseminated BCG infections 4 hours 4 Skin tuberculosis-like lesions 5 Pyogenic (ymphadenitis) 5 Pyogenic (ymphadenitis) 4 months 6 Meningitis (only caused by BCG) 7 days 7 Others 2 Seizure 1 Anaphylaxis 2 Seizure 2 Seizure 4 hours 2 McHambocytopenic purpura 2 Se days 3 Guillain-Barré syndrome 2 Se days 4 Thrombocytopenic purpura 2 Se days 5 Various Symptoms, mainly pain or movement disorders 4 hours 7 Others 2 Anthorns 8 Aseptic mennigitis (accompanied by herpes zoster) 4 hours 9 Abgris 2 Se days 4 Multiple sclerosis 2 Se days 5 Guillain-Barré syndrome 2 Se days 6 Othic neuritis 2 Se days 7 Peripheral neuropathy 2 Se days 8 Othic neuritis 2 Se days <td>4 Seizure 7 days 6 Others - 4 hours 1 Anaphylaxis - 4 hours 2 Disseminated BCG infection 1 year 3 BCG osteritis (osteomyelitä/periositiis) 2 years 4 Skin tuberculosis-like lesions 3 months 5 Pyogenic lymphadenitis 4 months 6 Meningitis (only caused by BCG) - 7 Others 4 hours 2 Seizure 2 days 3 Thrombocytopenic purpura 4 hours 2 ADEM 2 days 3 Cullain-Bare's syndrome 28 days 5 Various Symptoms, mainly pain or movement disorders - 7 Others - 1 Anaphylaxis 2 days 5 Various Symptoms, mainly pain or movement disorders - 1 Anaphylaxis 2 days 2 AbEM 4 hours 3 Aseptic meningitis (accompanied by herpes zoster) - 4 Others - 3 Multiple sclerosis 28 days 4 Myelitis 2 days 5 Guillain-Barré syndrome 2 days 6 Optic neuritis 2 days</td> <td></td> <td></td> <td>3 Encephalitis/encephalopathy</td> <td>28 days</td> <td>l Abnormal perception</td>	4 Seizure 7 days 6 Others - 4 hours 1 Anaphylaxis - 4 hours 2 Disseminated BCG infection 1 year 3 BCG osteritis (osteomyelitä/periositiis) 2 years 4 Skin tuberculosis-like lesions 3 months 5 Pyogenic lymphadenitis 4 months 6 Meningitis (only caused by BCG) - 7 Others 4 hours 2 Seizure 2 days 3 Thrombocytopenic purpura 4 hours 2 ADEM 2 days 3 Cullain-Bare's syndrome 28 days 5 Various Symptoms, mainly pain or movement disorders - 7 Others - 1 Anaphylaxis 2 days 5 Various Symptoms, mainly pain or movement disorders - 1 Anaphylaxis 2 days 2 AbEM 4 hours 3 Aseptic meningitis (accompanied by herpes zoster) - 4 Others - 3 Multiple sclerosis 28 days 4 Myelitis 2 days 5 Guillain-Barré syndrome 2 days 6 Optic neuritis 2 days			3 Encephalitis/encephalopathy	28 days	l Abnormal perception
6 Others 28 days 6 Others 4 hours 1 Anaphylaxis 4 hours 2 Disseminated BCG infection 2 years 3 BCG ostelia (seteonyelitis/periostitis) 2 years 4 Skin tuberculosis-like lesions 3 months 5 Pyogenic lymphadenitis 4 months 6 Meningitis (only caused by BCG) - 7 Others 4 hours 2 Scizure 2 days 4 Others 4 hours 2 ADEM 2 days 4 Others 4 hours 5 Vasovagal reaction (accompanied by syncope) 28 days 6 Various Symptoms, mainly pain or movement disorders - 7 Others - 1 Anaphylaxis 2 days 2 AbEM 4 hours 2 Aben by asyncome purpura 2 days 3 Aseptic meningitis (accompanied by herpes zoster) - 4 Others - 1 Anaphylaxis 2 days 2 ADEM 4 hours 3 Multiple sclerosis 28 days 4 Others - 3 Multiple sclerosis	6 Others 28 days 6 Others 4 hours 1 Anaphylaxis 4 hours 2 Disseminated BCG infection 2 years 3 BCG ostelials (sectionyellis/periostitis) 2 years 4 Skin tuberculosis-like lesions 3 months 5 Wegenic lymphadenitis 4 months 6 Meningitis (only caused by BCG) - 7 Others 4 hours 2 Seizure 28 days 4 Others 4 hours 2 ADEM 4 hours 2 ADEM 28 days 4 Thrombocytopenic purpura 28 days 5 Vasovagal reaction (accompanied by syncope) 30 minutes 6 Various Symptoms, mainly pain or movement disorders - 7 Others - 1 Anaphylaxis 28 days 2 ADEM 4 hours 3 Abeptic memingitis (accompanied by herpes zoster) - 4 Others - 2 ADEM - 3 Multiple sclerosis - 4 Myelitis - 5 Guillain-Barré syndrome - 6 Guillain-Barré syndrome<			4 Seizure	7 days	m Thrombocytopenic purpura
Anaphylaxis	Anaphylaxis			5 Thrombocytopenic purpura	28 days	n vascuntis o Impaired liver fination
Disseminated BCG infection	Disseminated BCG infection			6 Others 1 Anonhulovis	- A bossus	p Nephrotic syndrome
2 years 2 years 3 BCG ostelia (osteomyclistics) 2 years 3 BCG ostelia (osteomyclistics) 2 years 3 months 4 months 5 Pyogenic lymphadenitis 4 months 7 Others 7 Othe	2 years 2 years 3 BCG ostetics (osteomyclisty) 2 years 3 BCG ostetics (osteomyclisty) 2 years 4 months 5 Pyogenic lymphadenitis 6 Meningitis (only caused by BCG) - -			1 miapin taxis 9 Dissemin eted RCG infection	1 moor	q Asthma attack
4 Skin tuberculosis-like lesions 5 Pyogenic lymphadenitis 6 Meningitis (only caused by BCG) 7 Others 2 Seizure 3 Thrombocytopenic purpura 4 Hours 5 ADEM 6 Guillain-Barré syndrome 5 Various Symptoms, mainly pain or movement disorders 7 Others 7 Anothers 8 Aseptic meningitis (accompanied by herpes zoster) 7 Others 8 Amelyikis 9 ADEM 9 Autoritis 1 Anaphylaxis 9 Aseptic meningitis (accompanied by herpes zoster) 1 Anaphylaxis 9 ADEM 9 Aseptic meningitis (accompanied by herpes zoster) 1 Anaphylaxis 9 ADEM 9 Aseptic meningitis (accompanied by herpes zoster) 1 Anaphylaxis 9 ADEM 9 Aseptic meningitis (accompanied by herpes zoster) 1 Anaphylaxis 9 ADEM 9 Aseptic meningitis (accompanied by herpes zoster) 1 Anaphylaxis 9 AGENERAL SYNGROME 9 ASEPTIC MENINGINES 9 AGAYS	4 Skin tuberculosis-like lesions 3 months 5 Pyogenic lymphadenitis 4 months 6 Meningitis (only caused by BCG) - 7 Others 4 hours 2 Seizure 7 days 3 Thrombocytopenic purpura 4 hours 2 ADBA 28 days 4 Others 4 hours 2 ADBA 3 days 3 Guillain-Barré syndrome 28 days 5 Vasovagal reaction (accompanied by syncope) 30 minutes 6 Various Symptoms, mainly pain or movement disorders - 7 Others - 1 Anaphylaxis 28 days 2 ADBA 3 Aseptic meningitis (accompanied by herpes zoster) - 4 Others - 1 Anaphylaxis 28 days 2 ADBM 28 days 3 Multiple selerosis 28 days 5 Guillain-Barré syndrome 28 days 6 Optic neuritis 28 days 6 Optic neuritis 28 days 7 Peripheral neuropathy 28 days 8 Others 28 days 2 S days 28 days <tr< td=""><td></td><td></td><td>3 BCG osteitis (osteomyelitis/periostitis)</td><td>2 vears</td><td>r Interstitial pneumonia</td></tr<>			3 BCG osteitis (osteomyelitis/periostitis)	2 vears	r Interstitial pneumonia
5 Pyogenic lymphadenitis 4 months 6 Meningitis (only caused by BCG) - 7 Others - 1 Anaphylaxis 4 hours 2 Seizure 28 days 4 Others 4 hours 2 ADEM 28 days 4 Thrombocytopenic purpura 28 days 5 Vasovagal reaction (accompanied by syncope) 30 minutes 6 Various Symptoms, mainly pain or movement disorders - 7 Others - 1 Anaphylaxis - 2 Abben 4 hours 2 Abben - 4 Others - 1 Anaphylaxis - 2 Abben - 4 Others - 1 Anaphylaxis - 2 ADEM - 4 Myelitis - 5 Guillain-Barré syndrome 28 days 6 Guillain-Barré syndrome 28 days 6 Optic neuritis 28 days 7 Peripheral neuropathy 28 days 7 Peripheral neuropathy - 2 Abben -	5 Pyogenic lymphadenitis 4 months 6 Meningitis (only caused by BCG) - 7 Others - 1 Anaphylaxis 4 hours 2 Seizure 28 days 3 Thrombocytopenic purpura - 4 Others 2 days 3 Gullain-Barré syndrome 2 days 4 Thrombocytopenic purpura 2 days 5 Vasovagal reaction (accompanied by syncope) 30 minutes 6 Various Symptoms, mainly pain or movement disorders - 7 Others - 1 Anaphylaxis - 2 Abeptic meningitis (accompanied by herpes zoster) - 4 Others - 1 Anaphylaxis 2 days 2 Abeptic meningitis (accompanied by herpes zoster) - 4 Others - 3 Multiple sclerosis 2 days 4 Myelitis 2 days 5 Guillain-Barré syndrome 2 days 6 Optic neuritis 2 days 7 Peripheral neuropathy 2 days 8 Others -			4 Skin tuberculosis-like lesions	3 months	s Mucocutaneous ocular syndrome
6 Meningtitis (only caused by BCG) 1 Anaphylaxis 2 Seizure 3 Thrombocytopenic purpura 4 A hours 2 ADEM 2 ADEM 3 Guillain-Barré syndrome 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 ADEM 4 Others 1 Anaphylaxis 2 ADEM 5 ADEM 6 Optic meningtis (accompanied by herpes zoster) 1 Anaphylaxis 2 Adeays 6 Optic neuritis 6 Optic neuritis 7 Reripheral neuropathy 2 8 days 8 Others 9 Adeays 9 Adeays 1 Anaphylaxis 2 8 days 2 8 days 3 Rultiple reaction (accompanied by herpes zoster) 1 Anaphylaxis 2 8 days 3 Adeays 4 Abelitis 5 Chillain-Barré syndrome 6 Optic neuritis 7 Reripheral neuropathy 5 Selays 7 Reripheral neuropathy 8 Reripheral neuropathy 8 Reripheral neuropathy	6 Meningtitis (only caused by BCG) 1 Anaphylaxis 2 Seizure 3 Thrombocytopenic purpura 4 Others 1 Anaphylaxis 2 ADEM 2 ALBEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Aseptic meningtis (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Aseptic meningtis (accompanied by herpes zoster) 4 Hours 2 AbEM 4 Hours 2 ABEM 6 Whitiple sclerosis 8 Multiple sclerosis 9 Adays 6 Guillain-Barré syndrome 1 Anaphylaxis 2 Aben 2 Aben 3 Aseptic meningtis (accompanied by herpes zoster) 4 Hours 5 Aben 5 Aseptic meningtis (accompanied by herpes zoster) 6 Others 7 Others 8 Aseptic meningtis (accompanied by herpes zoster) 7 Anaphylaxis 8 Aseptic meningtis (accompanied by herpes zoster) 7 Anaphylaxis 8 Aseptic meningtis (accompanied by herpes zoster) 7 Anaphylaxis 8 Aseptic meningtis (accompanied by herpes zoster) 8 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abens 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abours 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abours 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abours 9 Aseptic meningtis (accompanied by herpes zoster) 9 Abours 9 Ab			5 Pyogenic lymphadenitis	4 months	t Uveitis
1 Anaphylaxis 2 Seizure 2 Seizure 2 Seizure 3 Thrombocytopenic purpura 4 Others 1 Anaphylaxis 2 ADEM 2 ADEM 3 Guillain-Barré syndrome 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 ADEM 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Asultiple sclerosis 4 Aburs 5 Guillain-Barré syndrome 5 Guillain-Barré syndrome 6 Optic neuritis 6 Optic neuritis 7 Peripheral neuropathy 8 Others 9 Agays 9 Authoritis 1 Anaphylaxis 1 Anaphylaxis 2 ADEM 2 Agays 3 Authiple sclerosis 3 Aseptic meningitis (accompanied by herpes zoster) 4 Aburs 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	1 Anaphylaxis 2 Seizure 2 Seizure 3 Thrombocytopenic purpura 4 hours 2 ADEM 2 ADIM 2 ADIM 2 Abisovagal reaction (accompanied by syncope) 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 ADEM 3 Asceptic meningitis (accompanied by herpes zoster) 4 A hours 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Guillain-Barré syndrome 7 Others 8 Authiple sclerosis 9 Adays 8 Authiple sclerosis 9 Adays 9 Adays 7 Peripheral neuropathy 9 Coptic neuritis 9 Adays 9 Others 9 Adays 9 Others 9 Adays 9			6 Meningitis (only caused by BCG)		u Arthritis Collistitis
1 Anaphylaxis 4 hours 2 Seizure 7 days 3 Thrombocytopenic purpura 4 hours 4 Others 28 days 5 ADEM 28 days 3 Guillain-Barré syndrome 28 days 5 Vasovagal reaction (accompanied by syncope) 30 minutes 6 Various Symptoms, mainly pain or movement disorders - 7 Others - 1 Anaphylaxis 2 Abertic meningitis (accompanied by herpes zoster) 4 Others - 1 Anaphylaxis 2 AbEM 2 ADEM 4 hours 3 Aseptic meningitis (accompanied by herpes zoster) - 4 Others - 1 Anaphylaxis 28 days 2 ADEM 28 days 3 Multiple sclerosis 28 days 4 Myelitis 28 days 5 Guillain-Barré syndrome 6 Optic neuritis 6 Optic neuritis 28 days 7 Peripheral neuropathy 28 days 8 Others 28 days	1 Anaphylaxis 4 hours 2 Seizure 7 days 3 Thrombocytopenic purpura - 1 Anaphylaxis 28 days 2 ADEM 28 days 3 Guillain-Barré syndrome 28 days 4 Thrombocytopenic purpura 28 days 5 Vasovagal reaction (accompanied by syncope) 30 minutes 6 Various Symptoms, mainly pain or movement disorders - 7 Others - 1 Anaphylaxis 28 days 2 ADEM 4 hours 3 Aseptic meningitis (accompanied by herpes zoster) - 4 Others - 3 Multiple sclerosis 28 days 4 Myelitis 28 days 5 Guilain-Barré syndrome 28 days 6 Optic neuritis 28 days 7 Peripheral neuropathy 28 days 8 Others 28 days			7 Others		w Vasovagal reaction
1 Anaphylaxis 2 Seizure 3 Thrombocytopenic purpura 4 Others 1 Anaphylaxis 2 ADEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 6 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	1 Anaphylaxis 2 Seizuee 3 Thrombocytopenic purpura 4 Others 1 Anaphylaxis 2 ADEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others					x It other than a-w, list symptom name
2 Seizuwe 3 Thrombocytopenic purpura 4 Others 1 Anaphylaxis 2 ADEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	2 Seizuwe 3 Thrombocytopenic purpura 4 Others 1 Anaphylaxis 2 ADEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Wyelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others		Haemophilus Influenzae type b	1 Anaphylaxis	4 hours	
4 Others 1 Anaphylaxis 2 ADEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	4 Others 1 Anaphylaxis 2 ADEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			2 Seizure 3 Thromboortonenie mirmine	7 days	
1 Anaphylaxis 2 ADEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	1 Anaphylaxis 2 ADEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			4 Others	Lo uays	
2 ADEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	2 ADEM 3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Asseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Wyelitis 6 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			1 Anaphylaxis	4 hours	
3 Guillain-Barré syndrome 4 Thrombocytopenic purpure 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	3 Guillain-Barré syndrome 4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 6 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			$2 \mathrm{ADEM}$	28 days	
4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	4 Thrombocytopenic purpura 5 Vasovagal reaction (accompanied by syncope) 6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			3 Guillain-Barré syndrome	28 days	
6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	6 Various Symptoms, mainly pain or movement disorders 7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			4 Thrombocytopenic purpura $5 \text{ Vecore and } poortion (constant and by surposed)$	28 days 30 minutes	
7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	7 Others 1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 6 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			6 Various Symptoms, mainly pain or movement disorders		
1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	1 Anaphylaxis 2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			7 Others		
2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	2 Thrombocytopenic purpura 3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			1 Anaphylaxis	4 hours	
3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Annaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	3 Aseptic meningitis (accompanied by herpes zoster) 4 Others 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			2 Thrombocytopenic purpura	28 days	
1 Annaphylaxis 1 AnbEM 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	1 Anaphylaxis 1 Anaphylaxis 2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			3 Aseptic meningitis (accompanied by herpes zoster)	1	
2 ADEM 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others	2 Anchy, June 2 2 Anchy, June 2 2 Anchy, June 3 Multiple sclerosis 4 Myelitis 5 Guillain-Barré syndrome 6 Optic neuritis 7 Peripheral neuropathy 8 Others			4 Curers 1 Ananhylaxis	- 4 hours	
3 Multiple sclerosis 28 days 4 Myelitis 28 days 5 Guillain-Barré syndrome 28 days 6 Optilis our distribution 28 days 7 Peripheral neuropathy 28 days 8 Others -	3 Multiple sclerosis 28 days 4 Myelitis 5 Guillain-Barré syndrome 28 days 6 Optic neuritis 7 Peripheral neuropathy 28 days 8 Others			2 ADEM	28 days	
4 Myelitis 28 days 5 Guillain-Barré syndrome 28 days 6 Optic neuritis 28 days 7 Peripheral neuropathy 28 days 8 Others -	4 Myelitis 28 days 5 Guillain-Barré syndrome 28 days 6 Optic neuritis 7 Peripheral neuropathy 28 days 8 Others			3 Multiple sclerosis	28 days	
5 Guillain-Barré syndrome 28 days 6 Optic neuritis 28 days 7 Peripheral neuropathy 28 days 8 Others	5 Guillain-Barré syndrome 28 days 6 Optic neuritis 7 Peripheral neuropathy 28 days 8 Others			4 Myelitis	28 days	
6 Optic neuritis 28 days 7 Peripheral neuropathy 28 days 8 Others	6 Optic neuritis 7 Peripheral neuropathy 8 Others			5 Guillain-Barré syndrome	28 days	
7 Peripheral neuropathy 28 days 8 Others -	7 Peripheral neuropathy 28 days 8 Others			6 Optic neuritis	28 days	
c carer o	Contes			7 Peripheral neuropathy 8 Others	28 days	
				Ocarers		

Disease	Symptom	Period to Onset	Symptoms
Rotavirus	1 Anaphylaxis	4 hours	
	z intussusception 3 Others	Zi days -	
Influenza	1 Anaphylaxis	4 hours	
	2 ADĒM	28 days	
	3 Encephalitis/encephalopathy	28 days	
	4 Seizure	7 days	
	5 Myelitis	28 days	
	6 Guillain-Barré syndrome	28 days	
	7 Optic neuritis	28 days	
	8 Thrombocytopenic purpura	28 days	
	9 Vasculitis	28 days	
	10 Impaired liver function	28 days	
	11 Nephrotic syndrome	28 days	
	12 Asthma attack	24 hours	
	13 Interstitial pneumonia	28 days	
	14 Mucocutaneous ocular syndrome	28 days	
	15 Acute generalized exanthematous pustulosis	28 days	
	16 Others		
Pneumococcal(Older people)	1 Anaphylaxis	4 hours	
	2 Guillain-Barré syndrome	28 days	
	3 Thrombocytopenic purpura	28 days	
	4 Necrosis or ulceration at the injection site	28 days	
	5 Cellulitis (symptoms similar to this, including those.	7 davs	
	extending from the upper arm to the forearm)	•	
	6 Others		
Coronavirus Disease 2019	1 Anaphylaxis	4 hours	
(COVID-19)	2 Thrombosis (including thromboembolism)	28 days	
	(limited to those with thrombocytopenia) (TTS)		
	3 Myocarditis	28 days	
	4 Pericarditis	28 days	
	5 Febrile seizure	7 days	
	6 Others		

TABLE 1. (Continued)

Table 2. Reporting Items

Vaccine Categories	Routine Vaccine Temporary Vaccine/Voluntary Vaccine
Patient information	Name or initials/sex/age at time of vaccination/address/date of birth
Information about the reporter	Name of medical institution/phone number/address
Vaccinated location	Name of medical institution/address
Vaccine information	Vaccine types/lot number/ marketing authorization holders/vaccine doses
Situation at the time of vaccination	Date of vaccination/birth weight/body temperature before vaccination
	Family history/points of concern of Prevaccination Screening Questionnaire
Information about the symptom	Symptoms/date of onset/causal relationship with vaccines/possibility of other factors
Severity of symptoms	Severe (death, disability, hospitalization, etc)/not severe
Outcomes	Recovered/recovering/not recovered/sequelae/death/unknown
Opinion of the reporter	
Number of reports	1st report/2nd report/3rd report or more

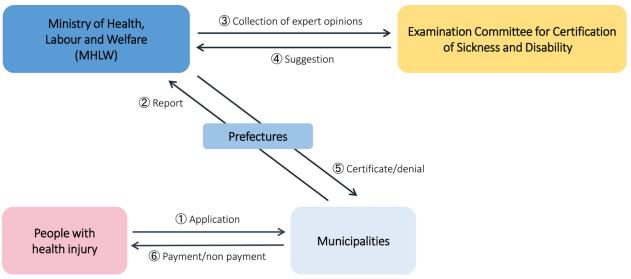


FIGURE 2. Structure of relief system for injury to health with vaccination.

REFERENCES

- Ministry of Health, Labour and Welfare. Reporting forms of adverse events following immunization from healthcare professionals. Available at: https:// www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou20/hukuhannou_houkoku/index.html. Accessed March 20, 2023.
- BRIGHTON COLLABORATION CASE DEFINITIONS. Available at: https://brightoncollaboration.us/category/pubs-tools/case-definitions/. Accessed August 19, 2023.
- Ministry of Health, Labour and Welfare. Health Sciences Council and the Pharmaceutical Affairs and Food Sanitation Council (joint council). Available at: https://www.mhlw.go.jp/stf/shingi/shingi-kousei_284075. html
- Ministry of Health, Labour and Welfare. Health status survey after immunization. Available at: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryyou/kenkou/kekkaku-kansenshou/yobou-sesshu/syukeihou.html. Accessed May 14, 2023.
- Fujiwara Y, Onda Y, Hayashi S. No-fault compensation schemes for COVID-19 medical products. *Lancet*. 2021;397:1707–1708.

- Ministry of Health, Labour and Welfare. The Relief System for Injury to Health with Vaccination. Available at: https://www.mhlw.go.jp/stf/seisakunitsuite/ bunya/vaccine_kenkouhigaikyuusai.html. Accessed March 20, 2023.
- Ministry of Health, Labour and Welfare. Number of people certified under the relief system for immunization. Available at: https://www.mhlw.go.jp/ topics/bcg/other/6.html.
- Ministry of Health, Labour and Welfare. Examination Committee for Certification of Sickness and Disability. Available at: https://www.mhlw. go.jp/stf/shingi/shingi-shippei_127696_00001.html.
- Ministry of Health, Labour and Welfare. Health Sciences Council (Immunization Advisory Committee). Available at: https://www.mhlw.go.jp/stf/newpage_09097.html.
- Kamiya H, Kamidani S, Saitoh A. An introduction to the Japanese immunization program: past, present, and future perspectives. *Pediatr Infect Dis J.* 2023;42:e154–e157.
- Pharmaceuticals and Medical Devices Agency. Relief System for adverse reactions to drugs. Available at: https://www.pmda.go.jp/relief-services/ adr-sufferers/0001.html. Accessed October 8, 2023.