

# The Current State of Immunization Administration in Japan

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## Abstract

Immunization in Japan is administered in accordance with the Preventative Vaccination Law. Its purpose is to “carry out immunization in order to prevent outbreaks of infectious diseases or epidemics, contributing to the improvement and promotion of public health as well as providing swift relief for health damages resulting from vaccinations.” Since its enactment in 1948, Japan’s immunization system has undergone numerous legal reforms to enhance the system through redefinitions of target diseases and target populations and by other improvements. The reforms include, for example, the change from compulsory to voluntary immunizations under the 1994 revision, and the addition of seasonal influenza as a target disease under the 2001 revision. This paper presents the current outline of Japan’s immunization system, reports recent changes that surrounds immunization such as the development and introduction of new vaccines, and suggest the future shape of immunization in Japan.

**Key words** Preventive Vaccination Law, Recommended vaccinations, Relief System for Injury to Health with Vaccination

## Introduction

Enacted in 1948, the Preventive Vaccination Law (hereafter the Law) was established in order to “carry out immunization in order to prevent outbreaks of infectious diseases or epidemics, contributing to the improvement and promotion of public health as well as providing swift relief for health damages resulting from vaccinations.” Since its enactment, the law has undergone numerous legal reforms, such as revisions of target diseases and target populations, to improve Japan’s immunization system. The basic framework for the current immunization system is based on the 1993 Public Health Council Report entitled “The Future Form of Immunization.”

This paper first examines the basic framework of the current immunization system in Japan and then report recent movements regarding public administration of immunizations in the nation.

## Basic Structure of Japan’s Current Immunization System

### Recommended vaccinations

In the past, immunizations for the general public were compulsory. However, because of the desirability of promoting vaccination by seeking understanding and cooperation from the general public and raising awareness so that people would undergo vaccination voluntarily, under the current immunization system the responsibility of unvaccinated persons has been changed to “endeavor to be vaccinated” (cooperative responsibility). Furthermore, national and local public agencies are to fully recommend vaccination, undertaking education and advertising regarding the characteristics of target diseases as well as the necessity and effectiveness of immunization.

Under the Law, immunization is divided into regular and irregular vaccinations with different

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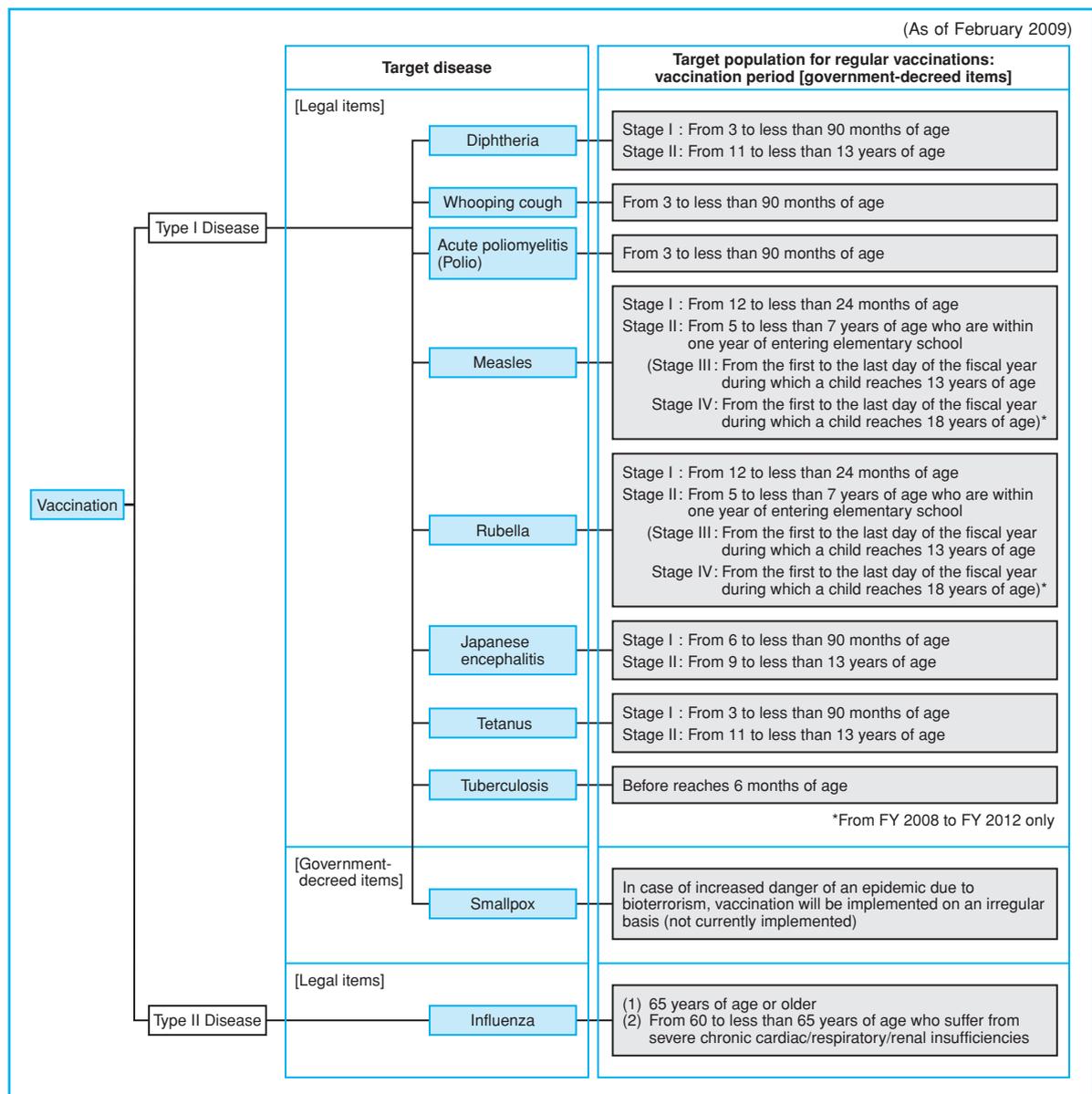


Fig. 1 Regular vaccination schedules

conditions and methods of administration. Given the current situation concerning infectious diseases, from a public health standpoint there is no immediate threat that a targeted disease under the Law would spread and the urgent need for irregular vaccinations would arise. Nonetheless, the implementation of irregular vaccinations is envisaged in the case of an outbreak of an infectious disease as the result of natural or artificial calamities such as bioterrorism. Smallpox is one

infectious disease that has been added as a target disease for irregular immunization due to the risk of possible outbreak by bioterrorism.

### Target diseases and vaccination periods

Target diseases for immunization and their vaccination periods are shown in Fig. 1.

When influenza was added to the list of target diseases under the 2001 revision of the Law, it was classified as a Type II Disease, while the other

**Table 1 Benefit types and amounts under the Relief System for Injury to Health with Vaccination**

(As of May 2008)

Benefit type	Benefit details	Benefit amount (improvements, etc.)	Benefits and others to base the amount on
<b>Type I Disease</b>			
Medical expenses	Paid to a person suffering from illness caused by vaccination.	Limited to the expenses for medical examinations, medications and treatment materials, medical procedures, surgery and other treatments or procedures, hospital or clinic stays, nursing, transportation, and other healthcare-related expenses. However, if the person is eligible to any medical benefits for the illness in question under laws such as Health Insurance Law, the benefit amount shall be limited to the amount of expenses minus the amount covered by other laws.	Equivalent to the self-paid amount within the amount calculated from the health insurance example
Medical allowance	Paid on a monthly basis to a person receiving a benefit for necessary miscellaneous medical expenses such as hospitalization, outpatient care, etc.	(From April 2008) Outpatient care (<3 days/mo): 33,800 yen Outpatient care (≥3 days/mo): 35,800 yen Hospitalization (<8 days/mo): 33,800 yen Hospitalization (≥8 days/mo): 35,800 yen Outpatient care and hospitalization in the same month: 35,800 yen.	Healthcare allowance (Law Concerning the Relief Atomic Bomb Survivors) • Same as the healthcare allowance • Healthcare allowance + 2,000 yen • Same as the Healthcare Allowance • Healthcare Allowance + 2,000 yen
Pension for rearing children with disabilities	Paid to a person rearing a child of less than 18 years of age who suffer from a certain level of disability due to illness caused by vaccination. The amount varies in accordance with the degree of disability. *For a Class 1 or 2 person living at home, nursing care is added.	(From April 2008) Class 1 (annually) [2,370,700 yen] <sup>†</sup> 1,531,200 yen Class 2 (annually) [1,784,900 yen] <sup>†</sup> 1,225,200 yen	Pension for Rearing Children with Disabilities (Law for the IAA of Pharmaceuticals and Medical Devices Agency) • Approx. 1.8×(pension for rearing children with disabilities Class 1 amount) • Approx. 1.8×(pension for rearing children with disabilities Class 2 amount)
Disability pension	Paid to a person who are 18 years or over who suffer from a certain level of disability due to illness caused by vaccination. The amount varies in accordance with the degree of disability. *For a Class 1 or 2 person living at home, nursing care is added.	(From April 2008) Class 1 (annually) [5,736,700 yen] <sup>†</sup> 4,897,200 yen Class 2 (annually) [4,475,300 yen] <sup>†</sup> 3,915,600 yen Class 3 (annually) 2,937,600 yen	Disability pension (Law for the IAA of Pharmaceuticals and Medical Devices Agency) • Approx. 1.8×(Class 1 of disability pension amount) • Approx. 1.8×(Class 2 of disability pension amount) • Approx. 60% of the disability pension amount under the Preventive Vaccination Law
Lump-sum payment for death	Paid to the bereaved of a person who died due to illness caused by vaccination.	(From April 2008) 42,800,000 yen	Survivors' pension (Law for the IAA of Pharmaceuticals and Medical Devices Agency) • Approx. 1.8×(survivors' pension amount) (10 years)
Funeral expenses	Paid to the person who was the host to the funeral of a person who died due to illness caused by vaccination.	(From April 2008) 199,000 yen	Funeral expenses (Law Concerning the Relief Atomic Bomb Survivors) • Amount equal to the funeral expenses
*Additional amount for nursing care		(From April 2008) Class 1 (annually) 839,500 yen Class 2 (annually) 559,700 yen	Nursing allowance (Law Concerning the Relief Atomic Bomb Survivors) • Amount equal to the nursing allowance (moderate level) • Nursing allowance (moderate level) × 2/3

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eight diseases were classified as Type I Diseases. This legal distinction reflects the difference in objectives between the two types. The objective of Type I Disease immunization is a collective defense (social defense) for public health against an outbreak or epidemic of an infectious disease. On the other hand, the objective of Type II Disease immunization is to prevent individuals from contracting a disease and, if they do contract the disease, to reduce the severity of the disease,

thereby contributing to public health. In view of this point, the general public has no cooperative responsibility to be vaccinated against Type II Diseases under the Law.

### Improvement of pre-examinations and promotion of individual vaccinations

Vaccinations may not only cause occasional side-effects such as fever, redness/swelling, and rashes, but also in extremely rare cases cause

Table 1 (continued)

Benefit type	Benefit details	Benefit amount (improvements, etc.)	Benefits and others to base the amount on
Type II Disease			
Medical expenses and/or medical allowance	Equivalent to the benefit amount of medical expenses and/or medical allowance for a Type I Disease. However, the medical care covered shall be limited to such levels that require hospitalization in a hospital or clinic.		
Disability pension	Paid to a person who suffers from a certain level of disability due to illness caused by vaccination. The amount varies in accordance with the degree of disability.	(From April 2008) Class 1 (annually) 2,720,400 yen Class 2 (annually) 2,175,600 yen	Disability pension (Law for the IAA of Pharmaceuticals and Medical Devices Agency) • In consideration of the Disability Pension amount
Survivors' pension	Paid to the bereaved of a person who has died due to illness caused by vaccination. Paid only if the deceased was the financial provider for the bereaved. (Benefit is limited to 10 years maximum).	(From April 2008) (Annually) 2,378,400 yen	Survivors' pension (Law for the IAA of Pharmaceuticals and Medical Devices Agency) • In consideration of the survivors' pension amount
Lump-sum payment for survivors	Paid to the bereaved of persons who have died due to illness caused by vaccination. Paid only when the deceased was NOT the financial provider for the bereaved.	(From April 2008) 7,135,200 yen	Disability pension (Law for the IAA of Pharmaceuticals and Medical Devices Agency) • In consideration of the lump-sum payment for survivors amount
Funeral expenses	Equivalent to the funeral expenses amount for Type I Diseases.		

IAA = Incorporated Administrative Agency.

<sup>†</sup> The amount shown in square brackets [ ] is the amount after nursing care benefit has been added.

Notes: Periods of claims for vaccination-related complications due to Type II Diseases are as follows.

1. The period to claim for the medical expenses and/or medical allowances is limited to within two years from the time that the payment eligible for benefits is made.
2. The period of to claim for survivors' pensions and lump-sum payments for survivors is limited to two years from time that the person died due to vaccination, if the deceased had been already receiving medical expenses, medical allowance, and/or disability pension benefits for his/her illness or disabilities caused by the said vaccination while he/she was alive. Otherwise, the period to claim is within five years from the death.

This system was established through the 1976 revision of the Preventive Vaccination Law and other measures, in which benefits are paid to persons who suffer complications or disabilities or die as a result of vaccinations administered in accordance with the law after February 25, 1977. Benefits are also paid to those whose health is damaged as a result of vaccinations administered prior to February 25, 1977, after the enforcement of the revision.

death or serious side-effects like severe neurological damage. In order to minimize these side-effects as far as possible, regulations concerning pre-examinations and questionnaires have been included in the law, emphasizing their importance. Moreover, "individual vaccinations"—administered by a family physician who is familiar with the normal health status of the vaccinee after thorough consultation—are actively promoted.

#### Ascertainment of post-vaccination health status and vaccination side-effects

In order to study post-vaccination health status and vaccination side-effects, the Survey of Post-vaccination Health Status and Report of Vaccination Side-effects is being implemented.

For the Survey of Post-vaccination Health Status, the expected number of vaccinations for each vaccine for each reporting physician is decided before vaccination, and post-vaccination health status is monitored over a set observation

period for each vaccine in a prospective manner. The results of these surveys are provided widely to the general public to enable them to undergo vaccination based on a correct understanding of immunization, to contribute to the administration of more effective and safer vaccinations.

The Report on Vaccination Side-effects is submitted to the Ministry of Health, Labour and Welfare (MHLW) of Japan, when a physician diagnoses post-vaccination side-effects in a vaccinee or a municipality receives a report of adverse side-effects from a vaccinee or his/her guardian. The purpose of this reporting system is to gather and provide the information on health status changes incurred by people undergoing vaccination broadly to the general public, as well as to contribute to the future improvement of vaccination administration. This reporting system is implemented in accordance with the 1994 revision of the Law.

**Table 2 Number of people certified under Relief System for Injury to Health with Vaccination**

(As of the end of 2007; unit = person)

Vaccine	Medical expenses Medical allowance	Pension for rearing children with disabilities			Disability pension				Lump-sum payment for death Funeral expenses	Total
		Class 1	Class 2	Total	Class 1	Class 2	Class 3	Total		
Smallpox	42				122	53	25	200	32	274
D	1					1		1		2
P					1	1	1	3	1	4
DT	33								1	34
DP	3				15	9	1	25	6	34
DPT	155	5	2	7	15	13	4	32	15	209
Polio	27	1	11	12	19	29	38	86	7	132
Measles	99	4	2	6	12	3		15	14	134
MMR	1,032	0	1	1		2	1	3	3	1,039
Rubella	58								2	60
Influenza (Irregular)	94				9	6	5	20	18	132
Influenza (Regular)	8									8
Japanese encephalitis	124	5	4	9	8	10	5	23	6	162
Weil's Disease										
Typhoid/paratyphoid									1	1
BCG	385					1	1	2	1	388
Cholera										
Total	2,061	15	20	35	201	128	81	410	107	2,613

1. Those deceased who have been certified to receive the lump-sum payment for death and/or funeral expenses and also certified as having suffered from illness or disability under other benefit types are listed in the [Lump-sum Payment for Death/Funeral Expenses] column only.
2. Those alive who are certified as suffering from disabilities that qualify for the disability pension and also certified as suffering from illness or disability under other benefit types are listed in the [Disability Pension] column only.
3. Those alive who are less than 18 years of age, certified as suffering from disabilities that qualify for the pension for rearing children with disabilities, and also certified as suffering from illness under the medical expenses and/or medical allowance are listed in the [Pension for Rearing Children with Disabilities] column only.

(Source: <http://www.mhlw.go.jp/topics/bcg/other/6.html> [in Japanese])

### The Relief System for Injury to Health with Vaccination

The Relief System for Injury to Health with Vaccination is intended to provide relief in the very rare case that a person becomes ill or disabled or dies as a side-effect of vaccination. First introduced under the 1976 revision of the Law, this system was improved with the 1994 revision. Benefit types and amounts as of May 2008 are shown in **Table 1**, and the status of certification as of the end of 2007 is shown in **Tables 2 and 3**.

The process of certification starts from the municipality that receives the report of health damage following vaccination. The municipality first sets up a commission of inquiry comprising specialists and members of medical associations, etc. The commission collects information about the case, situation at the time of vaccination, and the condition of other children who were vacci-

nated, and organize them into documentation to be submitted to the MHLW via the prefectural government. This documentation is presented to the Examination Committee for Certification of Sickness and Disability established by the MHLW, which examines the causal relationship between the vaccination and the person's health status. The MHLW minister is to issue certification based on the results of this examination.

### Recent Movements Concerning Vaccination Administration

#### Promotion of measures against measles/rubella

Although the number of measles patients is in decline, the disease cannot be said to have been eradicated in Japan. Some people do not acquire immunity with only one vaccination, and there

**Table 3 Certification and evaluation status of Relief System for Injury to Health with Vaccination**

(As of the end of 2007)

Benefit type	Number of applications	Number of certifications					Number of rejected cases	Number of cases currently under evaluation
		Total	Transferred to disability pension	Transferred to lump-sum payment for death	Cases deemed not applicable after certified	Currently certified persons		
<b>Type I Disease</b>								
Medical expenses Medical allowance	2,445	2,235	—	1	—	2,234	206	4
Pension for rearing children with disabilities	491	421	350	22	9	40	70	0
Disability pension	481	450	—	38	1	411	30	1
Lump-sum payment for death Funeral expenses	127	107	—	—	—	107	20	0
Subtotal	3,544	3,213	350	61	10	2,792	326	5
<b>Type II Disease</b>								
Medical expenses Medical allowance	23	9	—	—	—	9	13	1
Disability pension	2	0	—	—	—	0	1	1
Survivors' pension Funeral expenses	2	0	—	—	—	1	1	0
Lump-sum payment for death Funeral expenses	2	1	—	—	—	1	1	0
Subtotal	29	10	0	0	0	10	17	2
Total	3,573	3,223	350	61	10	2,802	343	7

Under 2001 revision to the Preventative Vaccination Law, target diseases were classified as either Type I or Type II Diseases. Consequently, evaluation status has also been classified under either Type I or Type II Diseases.

has been a decline in booster effect due to the reduced number of natural infections of wild-strain viruses. In view of these facts, the midterm report compiled in March 2005 by Investigative Committee on Preventative Vaccination proposed the introduction of 2-dose vaccinations for measles in order to achieve stronger community immunity. The mid-term report also recommended 2-dose vaccinations for rubella as well for the same reasons as for the measles, plus to prevent the occurrence of congenital rubella syndrome. Based on these recommendations, the 2-dose program of MR vaccine was introduced since April 1, 2006, in which children receive MR vaccine at age 1 (referred as Stage I) and at ages 5–6 (Stage II).

However, in 2007 there was an outbreak of measles mainly amongst teenagers and people in their 20s, causing high schools and universities to cancel classes and created great confusion as measles vaccine and testing kits became difficult

to obtain. Consequently, the national government established Specific Policies for Preventing Infectious Disease with Regard to Measles (also called National Measles Elimination Plan) in December of 2007, strengthening measures against measles. Under this policy, the five years from April 2008 has been deemed a period of action for eradicating measles. During these five years from 2008 to 2012 only, children aged 12 to 13 (Stage III) and 17 to 18 (Stage IV) (equivalent to 1st year of junior high school and 3rd year of high school, respectively) are to receive the second dose of MR vaccine (excluding those who have unquestionably contracted measles or rubella or have already been vaccinated twice with both vaccines). Through these efforts, the Japanese Government aims to eradicate measles in the nation by Fiscal Year (FY) 2012 and ensure to maintain that status thereafter.

In FY 2008, the first year of this 5-year plan, two meetings of Committee for the Promotion

of Measures against Measles were held where trends in the vaccination rate were reported. At the end of December 2008, the national average of measles vaccination rate was 66.4% for Stage II, 66.1% for Stage III, and 58.2% for Stage IV. Currently, concerns have been raised that the target vaccination rate for measles eradication, 95%, can not be attained if this situation continues. Thus, Committee for the Promotion of Measures against Measles is strengthening collaboration with educational institutions and issuing declarations to promote the vaccination rate increase, through Committees for Promoting Measures against Measles established locally by the national and prefectural governments.

### **The future form of immunization in Japan**

Nowadays, with the development and introduction of new vaccines, the environment surrounding immunization is changing daily. At the Investigative Committee on Preventative Vaccination held on December 26, 2008, the Chairman proposed that, in regard to national vaccination policies, we would require highly influential mechanisms and strengthening of educational functions on the effectiveness and safety of vaccines in easily comprehensible approach to the general public. In the future, Investigative Committee on Preventative Vaccination will be discussing the manner in which vaccination programs are administered as well as implementation of separate vaccinations against individual diseases.