Vaccination and Children's Health

2025 Version

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Introduction

Children are often ill and sometimes become extremely sick; vaccination can protect them from several serious illnesses.

This brochure has been created to provide you with information about vaccination and to allow you to have your child vaccinated safely.

We hope that this brochure will enhance the health and growth of your child.

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The 2025 edition is based on revisions as of February 2025.

You can receive the latest information from your municipality (including special wards; the same applies below). This information is also available from the websites of the Ministry of Health, Labour and Welfare (https://www.mhlw.go.jp/english/) and the Japan Institute for Health Security (https://id-info.jihs.go.jp/en/).

In the event of amendments to laws or regulations, the Notice of Revision, etc. will be uploaded to our website (https://www.yoboseshu-rc.com).

1. Get your child vaccinated!

The immunity to diseases which mothers give their infants almost completely disappears 3 months after birth for pertussis and 12 months after birth for measles. Consequently, after these periods, infants must ward off disease by producing their own immunity. Vaccination supports this defense.

Children go outside more often and interact with more people as they grow; consequently, they are at higher risk of infection. We recommend that you learn about vaccination and have your child vaccinated for his/her health.

● Infections

Infections are diseases that occur when pathogens such as viruses and bacteria enter the body and multiply. Depending on the type of pathogen, a variety of symptoms may occur, such as fever, cough, headache, rash, and diarrhea.

2. What is vaccination?

"Vaccination" refers to the administration of a vaccine—typically by injection or orally—to help the body develop or enhance immunity against disease. There are two main types of vaccines: live attenuated vaccines, which use weakened forms of infectious viruses, bacteria, or the toxins they produce, and inactivated vaccines, which contain pathogens that have been killed or rendered inactive. Recently, COVID-19 vaccines have been developed using mRNA (messenger RNA), which serves as a blueprint for producing the spike protein found on the surface of the COVID-19 virus. Vaccination involves administering vaccines to protect individuals from infectious diseases and to prevent their spread within the community. Even if they contract an infectious disease, vaccinated individuals are more likely to avoid developing severe symptoms. Vaccines cannot be prepared for all infectious diseases. Due to their nature, vaccines cannot be produced for some viruses and bacteria at present, but research to develop vaccines is continuing worldwide.

3. Vaccination validity

Vaccination is performed to prevent a target disease or reduce its severity in the event it is contracted; however, immunity is not established in some children because of their characteristics and physical condition. If there is a desire to confirm whether immunity has been established, there are blood tests which measure the levels of antibodies in the blood.

In addition, with some vaccines, immunity gradually diminishes even after it has been established, and such vaccines require boosters at specific intervals to maintain long term immunity. (See 5. (3) Vaccine types and characteristics on page 5)

4. Routine vaccination and voluntary vaccination

Vaccination includes routine vaccination and voluntary vaccination. With regard to routine vaccination, the Preventive Vaccination Law defines the target diseases, subjects and vaccination schedules.

Vaccination is carried out during periods appropriate to each disease. Please refer to "List of recommended periods for routine vaccination (Category A disease)" on page 8 for recommended vaccination periods (standard vaccination periods).

Routine vaccination

Routine vaccinations are the vaccinations stipulated by the "Preventive Vaccination Law" and are divided into vaccinations for Category A and Category B diseases. As a general rule, the cost is paid by the local governments for those subject to vaccination against Category A diseases, so they can be vaccinated at public expense. Vaccination against Category B diseases may be partly covered by public expense. From January 30, 2013, special measures have been set for children who were unable to receive routine vaccination due to a long-term serious illness. For details, please check the information of your health center/municipal office.

Category A disease	The main focus is on mass prevention and prevention of serious illnesses. The individual is obliged to make an effort to receive the vaccination, and the guardian is obliged to make efforts to ensure the individual (child) is vaccinated. In both cases, the government recommends receiving the vaccination.

・Rotavirus infection ・Hepatitis B ・Pneumococcal infection in children ・Diphtheria
・Pertussis ・Tetanus ・Polio (acute poliomyelitis) ・Hib infection ・Tuberculosis (BCG)
・Measles ・Rubella ・Varicella ・Japanese encephalitis ・Human papillomavirus (HPV) infection

Category B disease	The main focus is on personal prevention. The individual is not obliged to make an effort to receive the vaccination, and the parent/guardian is not obliged to make efforts to ensure the individual (child) is vaccinated. In both cases, there is no government recommendation to receive the vaccination.
・Seasonal influenza infection* ・Pneumococcal infection in the elderly ・COVID-19 infection in the elderly ・Herpes zoster in the elderly	

* Vaccinations against seasonal influenza and COVID-19 infection for children are voluntary.

Voluntary vaccination

Voluntary vaccinations are vaccinations other than the "routine vaccinations" stipulated in the "Preventive Vaccination Law". As a general rule, the cost required for vaccinations is borne by the individual. Some local governments pay part or all of the cost depending on the need for vaccination. Please check the information of your health center/municipal office.

5. Let's make a vaccination plan for your child

(1) Notice of vaccination

Routine vaccination is carried out by the municipal office in accordance with the Preventive Vaccination Law. A notice of vaccination is usually sent to parents/guardians individually. Since the notice is sent on the basis of the Basic Resident Register and the Residence Card, make sure to submit a notification when a baby is born or when you move.

(2) Set a rough schedule for vaccination

Routine vaccinations are, in principle, given individually. Determine a specific schedule and order for vaccinations in consulting with your family doctor, after considering municipal programs, your child's physical condition, and the prevalence of diseases.

Note that some municipalities may offer mass vaccination (performed on specified dates at specified sites such as health centers) of the BCG vaccine.

(3) Vaccine types and characteristics

Vaccines used for immunization include live vaccine; inactivated vaccine; and for COVID-19, mRNA vaccine.

Live vaccine

Live vaccines are made of attenuated live bacteria and viruses (live bacteria and viruses whose pathogenicity has been weakened). Resistance (immunity) to the disease is established similarly to actually being infected by it. After vaccination, attenuated bacteria and viruses (bacteria and viruses whose pathogenicity has been weakened) start multiplying; consequently, vaccines can cause mild symptoms, including fever and rash, depending on the vaccine. It takes about one month to establish sufficient resistance (immunity). However, some vaccines require boosters because their resistance (immunity) may gradually decline and weaken.

Types of live vaccines	・Rotavirus vaccine ・BCG vaccine ・Measles-rubella (MR) vaccine ・Measles vaccine ・Rubella vaccine ・Varicella (chicken pox) vaccine ・Mumps vaccine ・Yellow fever vaccine ・Intranasal influenza vaccine ・Smallpox vaccine (mpox prevention)

Inactivated vaccine

Inactivated vaccines are made by killing the virus or bacteria, extracting the components required to develop resistance (immunity) and eliminating their virulence (pathogenicity). The bacteria and viruses do not multiply, and several shots are required to establish resistance (immunity). Two or three vaccine shots are given at certain intervals to establish a basic resistance (immunity), after which a booster is given several months to one year later to enhance resistance (immunity) to a sufficient level. However, the resistance (immunity) declines gradually. To keep the resistance (immunity) for a long time, a booster is required at certain intervals, depending on the characteristics of the vaccine.

Types of inactivated vaccines and toxoids	・Hepatitis B vaccine ・Pneumococcal vaccine ・5-in-1 vaccine (DPT-IPV-Hib) ・4-in-1 vaccine (DPT-IPV) ・3-in-1 vaccine (DPT) ・2-in-1 vaccine (DT) ・Inactivated poliovirus vaccine (IPV) ・Hib vaccine ・Japanese encephalitis vaccine ・Human papillomavirus vaccine ・Seasonal influenza vaccine ・Meningococcal vaccine ・Hepatitis A vaccine ・Rabies vaccine ・Tetanus toxoid (T) ・Tick-borne encephalitis vaccine ・Typhoid vaccine ・Herpes zoster vaccine ・Respiratory syncytial virus vaccine

mRNA vaccine

COVID-19 vaccines include novel mRNA vaccines, which are manufactured differently from conventional methods. These vaccines encapsulate mRNA (messenger RNA)—serving as a blueprint for the protein antigen found on the surface of the COVID-19 virus—within lipid nanoparticles. As they do not fall under the traditional categories of live attenuated or inactivated vaccines, they are classified separately. Inactivated COVID-19 vaccines are also in practical use. Live vaccines are also being developed.

Types of mRNA vaccines	・COVID-19 vaccine

(4) Intervals between different types of vaccines

On October 1, 2020, the vaccination intervals when receiving different vaccines were revised. There are no longer any restrictions on the interval between vaccinations except when administering two injectable live vaccines.

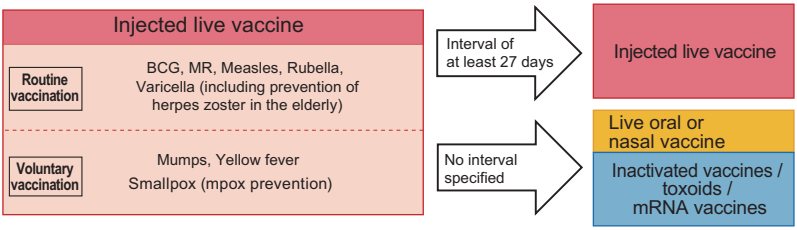
Vaccines used for immunization include live, inactivated, and mRNA vaccines. When injecting a live vaccine, it is necessary to observe a certain interval before injecting another live vaccine.

In certain cases, more than one type of vaccine may be received at the same time. Consult with your doctor thoroughly.

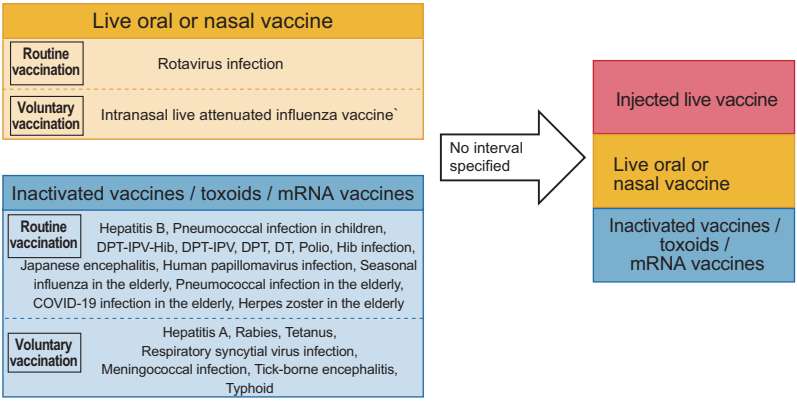
If your child is to be vaccinated several times with the same vaccine, please make sure that the specified intervals are adhered to.

Intervals between different types of vaccines

・Please follow the instructions provided in the package insert and other relevant materials regarding intervals between doses of the same vaccine.



* An interval of at least 27 days must elapse between two injected live vaccines, starting from the day after the first administration.
* There is no specified interval required between the administration of an injected live vaccine and subsequent administration of a live oral or nasal vaccine, inactivated vaccine, toxoid, or mRNA vaccine.



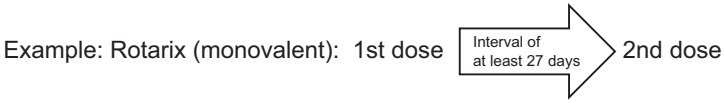
(Caution)

・Symptoms such as fever and swelling at the injection site may occur over a period of several days after vaccination. Even if within the permissible vaccination period, ensure that the individual is in good health—without symptoms such as fever or swelling at the injection site—before proceeding with vaccination.

・Vaccines may be administered simultaneously only when specifically approved by a physician.

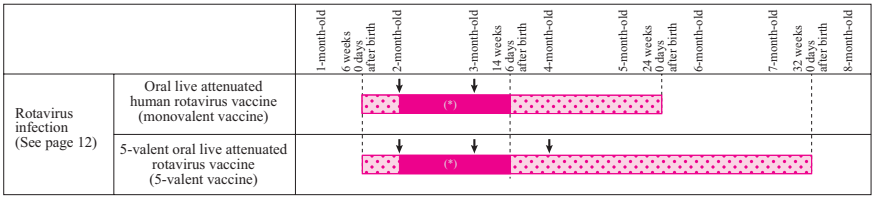
Vaccination intervals when receiving multiple doses of the same vaccine

・When receiving multiple doses of the same vaccine, it is necessary to observe the specified intervals for each vaccine.

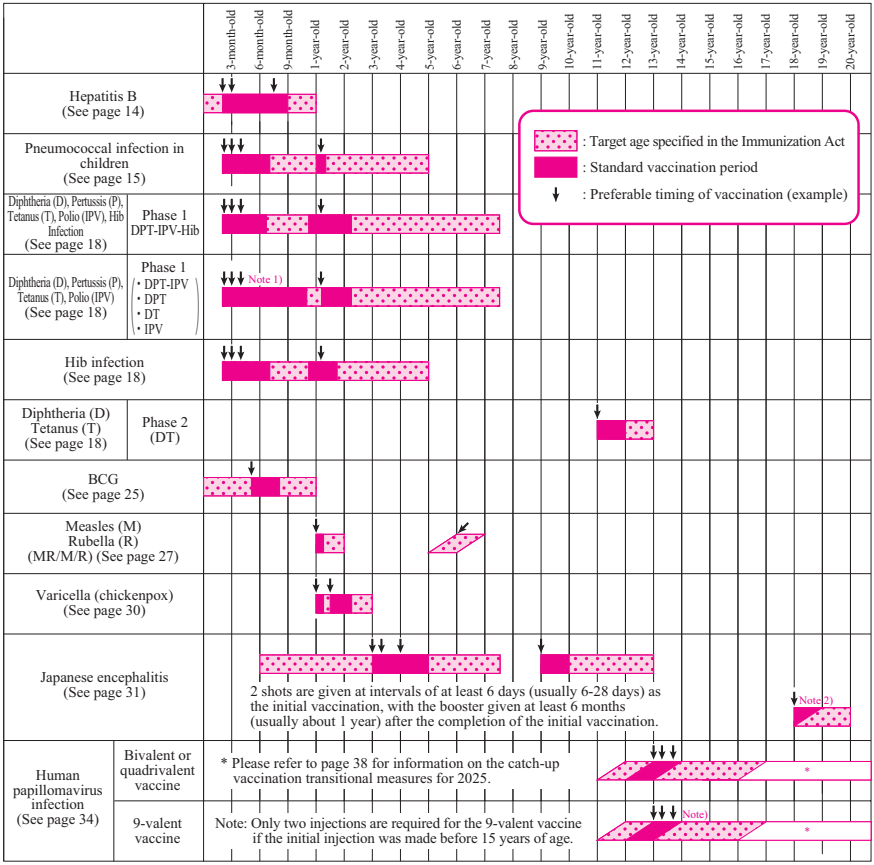


List of recommended periods for routine vaccination (Category A disease)

[Note] The starting date for calculating the vaccination interval is the day following the day of vaccination. Vaccination intervals are legally specified in days. For example, "an interval of one week" should be interpreted as "on or after the same day of the following week."



*: The standard period for the initial vaccination is from when the infant is 2 months old up to 14 weeks and 6 days after birth.



Note 1: If DT is used for phase 1, it is to be given no earlier than 3 months after birth.

Note 2: Persons born between April 2, 1995 and April 1, 2007 who were unable to receive the phase 1 or 2 vaccines are able to receive the missed doses as routine vaccinations, if they are under the age of 20.

6. Before having your child vaccinated

Please confirm the following before vaccination

1 Is your child in good health?
2 Do you understand the necessity, effectiveness, and potential adverse reactions of the vaccine that will be given to your child today?
If you have any questions, please write them down.
3 Did you bring your maternal and child health handbook with you?
4 Did you complete a vaccination screening questionnaire?

(1) General precautions

Vaccination should be performed when your child is in good health. Always take note of the physical condition and characteristics of your child. If you have any concerns, do not hesitate to consult your family doctor, healthcare center, or the municipal office in charge, in advance.

To have your child vaccinated safely, we recommend that you make the decision whether to receive the vaccination on the appointed day after taking the following into consideration:

a) Observe your child carefully from the morning on the day of vaccination, and confirm that he/she is well.
If your child is scheduled to receive a vaccination but seems unwell, consult your family doctor to determine whether to proceed with the vaccination.

b) Thoroughly read the information about vaccination provided by the municipal office so that you fully understand the necessity and possible adverse effects of the vaccines. If you have any questions, ask the doctor who is to vaccinate your child before vaccination.

c) Make sure to bring your maternal and child health handbook.

d) The screening questionnaire contains important information for the doctor in charge of vaccination. Please fill in the form completely and accurately.

e) We recommend that the child being vaccinated be accompanied by a parent/guardian who is familiar with the child's usual physical condition.

A child can only be vaccinated if a parent/guardian fully understands the effectiveness and potential adverse reactions to vaccination and agrees to have the child vaccinated.

(2) The following persons cannot receive vaccination:

a) A child with an obvious fever (37.5℃ or higher)

The vaccinating doctor and guardian (and the child) are to thoroughly check the health condition of persons presenting with a body temperature slightly higher than 37.5℃ due to such reasons as a high baseline body temperature, and make judgments accordingly as to whether to perform the vaccination.

b) A child with a serious acute illness

As a general rule, children with acute, severe illnesses should not be vaccinated on that day, as the course of such illness can be unpredictable.

c) A child who has had anaphylaxis to any component of the vaccine preparation to be given on that day

"Anaphylaxis" is an acute, severe systemic allergic reaction, usually within 30 minutes after vaccination, including excessive sweating, a swollen face, systemic severe urticaria, nausea, vomiting, hoarseness, and respiratory distress, resulting in shock.

d) Women eligible for the measles, rubella, varicella (chickenpox), and mumps vaccination and are known to be pregnant

This is a regulation not directly concerning children but important for persons who will receive voluntary vaccination.

e) As concerns the BCG vaccination (hereinafter referred to BCG), a child with a predisposition to keloids

f) Children eligible for rotavirus vaccination who have a clear history of intussusception, who have a congenital abnormality of the gastrointestinal tract (except for children who have completed treatment for said abnormality), or who have been found to have a severe combined immunodeficiency disease

g) Other conditions that a doctor considers inappropriate

Even if your child does not meet the above criteria a) to f), he/she cannot be vaccinated if a doctor decides that doing so would be inappropriate.

・Children who are eligible for the hepatitis B vaccination and who have received the hepatitis B immunoglobulin and hepatitis B vaccine after birth under health insurance

coverage as part of the mother-to-infant transmission prevention program are excluded from the routine vaccination program. However, subsequent vaccinations and related treatments will continue to be covered by health insurance.

(3) Children who require careful consideration in receiving a vaccination

Parents/guardians to whom the following may apply should have their child seen by their family doctor in advance to determine whether the child can be vaccinated. If vaccination is to take place, it should be performed by the family doctor, or at another medical institution provided a note or letter, etc. can be obtained from the family doctor.

a) A child who is being treated for a heart, kidney, liver, or blood disease, or a developmental disorder.

b) A child who has had a fever within 2 days of a previous vaccination or an allergic reaction, including rash and urticaria.

c) A child who has had a seizure in the past.

The decision of whether a child should be vaccinated depends on the age at which the seizure occurred, the presence or absence of fever, subsequent seizures, and the type of vaccine. Please consult the child's doctor before vaccination.

d) A child who has been diagnosed with immunodeficiency in the past or has a family member or relative with immunodeficiency (for example, a person who repeatedly had perianal abscesses as a baby).

e) A child who is allergic to the vaccine's components, such as eggs, antibacterial agents, and the stabilizers, which may be used in the culture process in vaccine manufacturing.

f) In the case of BCG vaccination, a child who is suspected to have been infected with tuberculosis in the past, such as having had extended contact with a tuberculosis patient in the family.

g) In the case of rotavirus vaccination, a child with an active gastrointestinal illness or gastrointestinal disorder such as diarrhea.

(4) General precautions after receiving vaccination

a) For 30 minutes after the vaccination, observe your child at the medical institution (facility) or ensure that a doctor can be contacted immediately. Acute adverse reactions,

although rare, may develop during that time.

b) Watch for possible adverse reactions for up to 4 weeks (for live vaccines and mRNA vaccines) or 1 week (for inactivated vaccines) after vaccination.

c) Keep the vaccination site clean. Bathing is allowed, but avoid rubbing the vaccination site.

d) Avoid strenuous physical activity on the day of vaccination.

e) If a child experiences an abnormal reaction at the vaccination site or has a change in physical condition after vaccination, consult a doctor immediately.

7. Diseases preventable by vaccination and vaccines

Each child has a unique physiological makeup. In rare cases, varying degrees of adverse reactions may occur. It is important for you to decide whether to have your child vaccinated after detailed consultation with your doctor, who understands the physical status of your child.

◆ Rotavirus infection

(1) Cause and course

Rotavirus is a cause of acute gastroenteritis seen around the world and often seen primarily in infants and children under the age of 5 years old. Primary symptoms include diarrhea, vomiting, and fever and may also occasionally be accompanied by dehydration, seizures, liver dysfunction, and renal failure, and, rarely, acute encephalopathy. It can infect and cause illness any number of times, regardless of age, but first-time infection during infancy causes the most serious illness, with repeated infection thereafter resulting in more and more mild illness.

(2) Rotavirus vaccines (live vaccines)

There are two rotavirus vaccines – the oral live attenuated human rotavirus vaccine (Rotarix®; hereafter referred to as the monovalent vaccine), which uses attenuated rotavirus; and the 5-valent oral live attenuated human rotavirus vaccine (RotaTeq®; hereafter referred to as the 5-valent vaccine), which uses reassortant rotavirus. Both vaccines provide about 80% protection from gastroenteritis caused by rotavirus infection, and about 95% protection from serious rotavirus infection.

Rotavirus can infect and cause illness any number of times, regardless of age, but first-time infection during infancy causes the most serious illness, with repeated infection thereafter

resulting in more and more mild illness. Accordingly, with the primary aim of preventing such first-time infection, vaccination is administered in early infancy.

With the first rotavirus vaccine introduced in the United States, it was found that intussusception, a serious illness in infants and young children, frequently occurred as an adverse reaction, and marketing of this product was discontinued. Both of the two varieties of rotavirus vaccine in use around the world today have been confirmed to have a lower risk of intussusception than the first rotavirus vaccine introduced in the United States via large-scale clinical trials.

The risk of intussusception is increased during the week after receiving the first rotavirus inoculation.

In comparing the risks (the occurrence of adverse reactions such as intussusception) and benefits (prevention of serious rotavirus infection) of rotavirus vaccination, it is believed that preventing rotavirus infection is more beneficial to children, and more and more countries around the world are introducing the rotavirus vaccines.

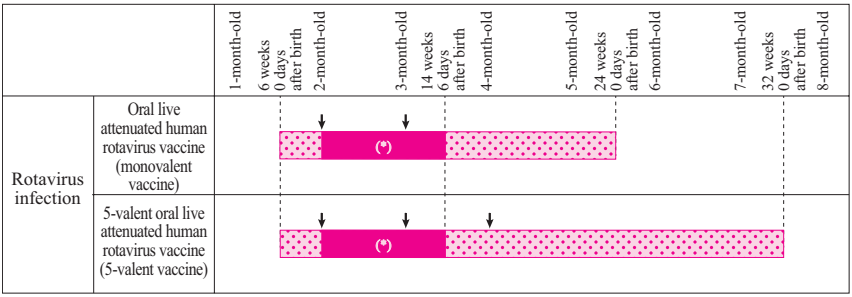
If you notice even one of the following in your child after rotavirus vaccination, consider the possibility of intussusception and consult with a doctor immediately: periodic dysphoria, abdominal pain, repeated vomiting, intense crying, or bloody stool.

The rotavirus vaccine was added to the routine vaccination program starting October 1, 2020, and children born on or after August 1, 2020, have been eligible for routine vaccination since then.

The inoculation ages and number of inoculations differ according to the type of vaccine used. The monovalent vaccine (Rotarix®) is given in 2 inoculations separated by an interval of 27 days or more for children between 6 weeks 0 days after birth and 24 weeks 0 days after birth. The 5-valent vaccine (RotaTeq®) is given in 3 inoculations separated by intervals of 27 days or more for children between 6 weeks 0 days after birth and 32 weeks 0 days after birth. Note that in order to avoid the period in which there is a high incidence of intussusception, it is considered desirable to complete the initial inoculation by 14 weeks 6 days after birth.

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0031% for the monovalent vaccine (Rotarix®) and 0.0021% for the 5-valent vaccine (RotaTeq®). (The incidence reported from April 1, 2013 to September 30, 2024. Source: January 2025 documents 2-27 and 2-28 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

(3) Vaccination schedule



*: The standard period for the initial vaccination is from when the infant is 2 months old up to 14 weeks and 6 days after birth.

◆ Hepatitis B

Since October 2016, the hepatitis B (HB) vaccine has been given as a routine vaccination to all children born on or after April 1, 2016. The cost of vaccinations to newborns of hepatitis B-positive (HBs antigen positive) mothers will continue to be covered by health insurance, and in the case of accidental exposure to hepatitis B positive blood etc., the cost of vaccinations will continue to be covered by workers' compensation or health insurance.

(1) Cause and course

When a person is infected by the hepatitis B (HB) virus, he or she may develop acute hepatitis and recover, or progress to chronic hepatitis. In some cases, fulminant hepatitis may occur with severe symptoms which may result in death. In other cases, the virus may hide in the liver without causing any obvious symptoms, and develop into chronic hepatitis, cirrhosis, or hepatic cancer after a period of years. It is known that the younger the patient, the less clear the symptoms of acute hepatitis and the more likely the virus will hide, resulting in persistent infection. Infections occur through mother-infant transmission from an HB virus positive (HBs antigen positive) mother to her newborn, through direct contact with HB positive blood or bodily fluids, or through sexual contact with an individual who is HB positive.

(2) Hepatitis B vaccine (inactivated vaccine)

Vaccination with the hepatitis B (HB) vaccine, especially in children, is aimed primarily at preventing persistent infection by the virus and the future potential occurrence of chronic

hepatitis, cirrhosis, or hepatic cancer, rather than at preventing hepatitis in the short term.

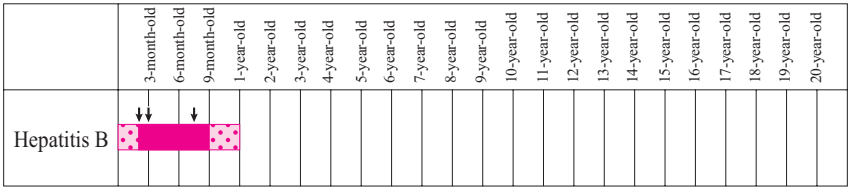
Previously, newborn infants of HB virus positive mothers were given the hepatitis B vaccine plus hepatitis B immunoglobulin as soon as possible after birth to prevent mother-to-child transmission. Now, however, in order to have more people receive the hepatitis B vaccine and reduce the number of future sufferers of chronic hepatitis, cirrhosis, and hepatic cancer, routine vaccination began in October 2016 for all children born on or after April 1, 2016, in addition to the mother-to-child transmission prevention program.

Note that the mother-to-child transmission prevention program will continue to be covered by health insurance.

Children eligible for routine HB vaccination are those born on or after April 1, 2016 and under 1 year of age, who are not subject to the Mother-to-child transmission prevention project. The standard schedule is between the time the child turns 2 months and up to 9 months, in which two subcutaneous injections are given with an interval of at least 27 days between the first and second injections, and another (i.e. third) subcutaneous injection given after an interval of at least 139 days after the first injection.

Adverse reactions to the HB vaccine have been reported in about 10% of people who received the vaccine to date, and include lethargy, headache, and swelling/redness/pain at the vaccination site, etc. However, the vaccine is being given to newborns and infants without problems. The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0009%. (The incidence reported from April 1, 2013 to September 30, 2024. Source: January 2025 documents 2-24 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

(3) Vaccination schedule



◆ Pneumococcal infection in children

(1) Cause and course

Streptococcus pneumoniae is one of two major causes of bacterial pediatric infections. This

is a bacterium carried deep in the noses of many children and occasionally causes bacterial meningitis, bacteremia, pneumonia, sinusitis, and otitis media.

Prior to the introduction of the vaccine, the prevalence of bacterial meningitis caused by Streptococcus pneumoniae was 2.6-2.9 out of a population of 100,000 aged less than 5 years. It was estimated that about 150 experienced meningitis per year*. Case fatality rate and frequency of long-term effects (e.g. hydrocephalus, deafness, mental disabilities) are higher than that of Hib-induced meningitis, with about 21% experiencing a poor prognosis. (*Cited from material provided by the Vaccination Working Group, Section of Infectious Diseases, Health Science Council of MHLW.) Now that the pneumococcal conjugate vaccine is in wide use, invasive infections such as pneumococcal meningitis have decreased dramatically.

(2) Pneumococcal conjugate vaccine (inactivated vaccine)

The pediatric pneumococcal conjugate vaccine (pneumococcal conjugate vaccine) was developed to prevent bacterial meningitis in children, including serotypes causing serious conditions in children.

This vaccine was first introduced in the United States as a 7-valent vaccine in 2000. In 2010, it was replaced by the 13-valent vaccine, which is now routinely used in over 100 countries worldwide.It has been reported in many countries that vaccination with this vaccine reduces bacterial meningitis and bacteremia. In Japan, the vaccine was authorized for use in November 2013, and the incidence of invasive pneumococcal disease has decreased similarly. Since April 2024, the 15-valent pneumococcal vaccine has been included in the routine vaccination program, and starting in October of the same year, the 20-valent vaccine has also been included in the routine vaccination. (The 13-valent vaccine, which had been used until then, was removed from the routine vaccination program in October 2024 following the manufacturer's decision to discontinue its supply.)

This vaccine may be given simultaneously with other vaccines when the physician determines it to be necessary and the child’s parent/guardian gives consent. Each vaccine can also be given separately.

Adverse reactions include local reactions such as erythema (57.3-66.2%) and swelling (45.1-50.9%), and systemic reactions including fever (39.4-55.6%). (For Prevenar 20®, refer to the package insert revised in August 2024 [2nd edition]; for Vaxneuvance®, refer to the package insert revised in February 2024 [4th edition].)

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0000% for the 20-valent vaccine and 0.0011% for the 15-valent vaccine. (The incidence reported from the

market launch to September 30, 2024. Source: January 2025 documents 2-20 and 2-21 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

Pneumococcal vaccination for children is administered according to the following methods, based on the child's age in months at the start of the initial vaccination. The standard vaccination procedure is as described in a) below:

In principle, the 20-valent vaccine is used, and the 15-valent vaccine can also be used for the time being. For children who have completed the first, second, or third vaccination using the 13-valent vaccine, the remaining vaccination should, in principle, be administered with the 20-valent vaccine; however, the 15-valent vaccine may also be used.

a) A child aged 2 to 7 months (not exceeding the first day of 7 months) at the time of initiating the initial vaccination.

   The initial vaccination is conducted using a 20-valent or 15-valent pneumococcal conjugate vaccine provided three times at intervals of at least 27 days usually by the time the child is 12 months of age. The booster is conducted once at an interval of at least 60 days after the initial vaccination, given no earlier than one day after the child turns 12 months (the standard vaccination period is between 12-15 months after birth). However, the second and third injection of the initial vaccination is to be given by the time the child is 24 months of age, and is not to be given if the child exceeds 24 months (the booster is allowed after this time). The second injection of the initial vaccination is to be given by 12 months of age. If the second dose is given after 12 months of age, the third injection of the initial vaccination is not to be given (the booster is allowed after this time).

b) A child aged 7 months (the second day of 7 months) to 12 months (not exceeding the first day of 12 months) at the initiation of the initial vaccination

   The initial vaccination is conducted using a 20- valent or 15-valent pneumococcal conjugate vaccine provided twice at intervals of at least 27 days usually by the time the child is 12 months of age. The booster is conducted once at an interval of at least 60 days after the initial vaccination 12 months after birth. However, the second injection of the initial vaccination is to be given by the time the child is 24 months of age, and is not to be given if the child exceeds 24 months (the booster is allowed after this time).

c) A child aged 12 (the second day of 12 months) to 24 months (not exceeding the first day of 24 months) at the initiation of the initial vaccination.

   The vaccination is conducted using a 20-valent or 15-valent pneumococcal conjugate vaccine provided twice at intervals of at least 60 days.

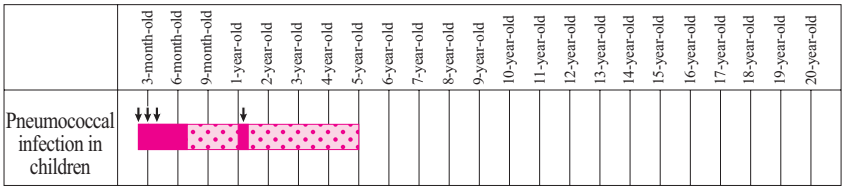
d) A child aged 24 (the second day of 24 months) to 60 months (not exceeding the first day of 60 months) at the initiation of the initial vaccination.

The vaccination is conducted using a 20-valent or 15-valent pneumococcal conjugate vaccine provided once.

A child who could not be vaccinated due to disease requiring long-term care is also vaccinated in this manner.

e) In principle, the same type of pneumococcal vaccine should be used to complete the vaccination series in each child. However, if there are unavoidable circumstances—such as when a child, after having received a certain number of doses, moves to a municipality where only the 20-valent vaccine is available, and the mayor of that municipality recognizes the reason—then the remaining doses in a child who began vaccination with the 15-valent vaccine may be administered using the 20-valent vaccine. If you have any questions regarding your child falling under this case, consult with your municipal office in charge of vaccination.

(3) Vaccination schedule



◆ Diphtheria, pertussis, tetanus, polio (acute poliomyelitis), and Hib infection

(1) Cause and course

a) Diphtheria

Diphtheria is caused by Corynebacterium diphtheriae and is spread by droplet infection.

The improved diphtheria-pertussis-tetanus vaccine (DPT) (acellular) was introduced to the market in 1981. Today, the annual incidence of diphtheria in Japan has been zero (0) for many consecutive years, but in the Asian region, epidemic outbreaks have been seen.

The bacterium infects mainly the throat but also the nasal cavity. Even when infection occurs, diphtheria causes symptoms in only about 10% of people, while the rest of those infected become asymptomatic carriers who can transmit the disease to other people. Symptoms include high fever, sore throat, a barking cough, and vomiting; a false membrane may also form in the throat which can cause asphyxia. Patients must be monitored carefully because the

bacterium produces a toxin that can cause a serious myocardial disorder or paralysis two to three weeks after the development of symptoms.

b) Pertussis

Pertussis is caused by Bordetella pertussis and is spread by droplet infection.

Since pertussis vaccination was begun in 1950, the number of patients has decreased, but in recent years, there have been cases of pertussis in children ranging from school age to adolescence as well as in adults characterized by persistent coughing. Such people are potential sources of infection to small children, and require caution since the disease can become serious, especially in newborns and infants.

Prototypical pertussis begins with symptoms mimicking a common cold. The child then begins to cough violently and repeatedly, with a flushed face. After coughing, the patient is forced to inhale rapidly, creating a whooping sound similar to a whistle. Usually, fever does not develop. Infants sometimes present with blue lips (cyanosis), seizures (fits) or suddenly stop breathing because they are unable to breathe due to coughing. Severe complications such as pneumonia or encephalopathy are likely to develop, and these diseases may lead to death in newborns or infants.

● Droplet infection

Droplet infection is the transmission of viruses and bacteria through coughing, sneezing, conversation, etc. Viruses and bacteria enveloped in sprays of saliva and airway secretions are spread through the air to people within one meter.

c) Tetanus

Clostridium tetani does not spread from person to person. The bacteria are usually found in soil and enter the body through wounds in the skin. The bacteria multiply in the body and produce a toxin, causing tonic muscle spasms. Tetanus is a serious disease that often begins with symptoms such as difficulty opening the mouth (lockjaw). As the condition progresses, it can lead to generalized tonic convulsion. If treatment is delayed, tetanus can be fatal. Half of all patients are infected through a small puncture wound not noticed by themselves or the people around them. As the bacteria are found in soil, opportunities for infection are constant. If a pregnant mother has immunity, the newborn is protected from tetanus during delivery.

d) Polio (acute poliomyelitis)

Polio (acute poliomyelitis) is also known as “infantile paralysis.” Pandemics occurred repeatedly in Japan until the early 1960s. Owing to vaccination, the last occurrence of a patient

paralyzed by a wild strain of the polio virus was in 1980. The WHO declared the eradication of poliomyelitis from the Western Pacific Region including Japan in 2000. At present, there are only two polio-endemic countries, Pakistan and Afghanistan, and global polio eradication seems no longer a dream, but the world remains vigilant against polioviruses.

The polio virus infects through the mouth and proliferates in the cells of the pharynx and small intestine. The polio virus is said to multiply for 4 to 35 days (mean: 7-14 days) in the cells of the small intestine. Viruses thus multiplied are excreted in feces and taken through the mouth of a person with no resistance (immunity) to the polio virus, multiply in the intesitine, resulting in infection from person to person. Most people who are infected with the polio virus are asymptomatic and gain lifelong protection (lifelong immunity). In some people who experience symptoms, the viral infection spreads via the blood to the brain and spinal cord, thereby causing paralysis. Out of 100 children infected with the polio virus, 5-10 experience symptoms like those of the common cold, accompanied by fever, and followed by headache and vomiting.

About 1 of 1,000-2,000 people infected with the polio virus experiences paralysis of the limbs. Some are permanently paralyzed or suffer from progression of symptoms, sometimes dying of respiratory distress.

e) Hib infection

Hib infection is a disease caused by a bacterium called Haemophilus influenzae type b. Haemophilus influenzae, especially Haemophilus influenzae type b, is a problematic pathogen for infants and small children, causing not only superficial infections such as otitis media, sinusitis, and bronchitis, but also serious deep (systemic) infections (also called invasive infections) such as meningitis, sepsis, and pneumonia. Prior to 2010, the incidence of meningitis caused by Hib was 7.1-8.3 out of a population of 100,000 aged less than 5 years. It was estimated that about 400 became infected with meningitis per year and about 11% of those experienced poor outcomes*. Children aged 4 months or more and less than 1 year accounted for a half of total patients. (*Cited from a material provided by the Vaccination Working Group, Section of Infectious Diseases, Health Science Council of MHLW.) Now that the Hib vaccine is widely used, invasive Hib disease is nearly unseen.

(2) Freeze-dried Haemophilus influenzae type b vaccine (Hib vaccine) (inactivated vaccine)

Haemophilus influenzae is classified into 7 types, with type b being the main cause of serious disease; consequently, type b is used for vaccination. This vaccine is used extensively throughout the world, and was authorized for use in Japan in December 2008 and made a routine vaccination in April 2013.

This vaccine may be given simultaneously with other vaccines when the physician determines it to be necessary and the child's parent/guardian gives consent. Each vaccine can also be given separately.

In Europe and the United States, invasive Hib infections decreased dramatically after the vaccine was introduced. Reduction has been similarly dramatic in Japan after introduction of routine vaccination, and Hib infections are now nearly unseen. The World Health Organization (WHO) highly recommended routine Hib vaccinations for infants and children in 1998; consequently, Hib vaccination has been introduced in more than 110 nations and its efficacy has been evaluated highly.

Adverse reactions (at the time of approval) are mainly local reactions including redness (44.2%), swelling (puffiness) (18.7%), induration (lump) (17.8%), and pain (5.6%); as well as systemic reactions including fever (2.5%), dysphoria (14.7%), and loss of appetite (8.7%). (See package insert [4th ver.] revised in August 2024)

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0019%. (The incidence reported from April 1, 2013 to September 30, 2024. Source: January 2025 documents 2-18 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

(2) Diphtheria, pertussis, tetanus, inactivated polio and Haemophilus influenzae type b 5-in-1 combination vaccine (DPT-IPV-Hib), Diphtheria, pertussis, tetanus and inactivated polio 4-in-1 combination vaccine (DPT-IPV), Diphtheria, pertussis and tetanus 3-in-1 combination vaccine (DPT), and diphtheria-tetanus 2-in-1 combination vaccine (DT) (inactivated vaccine)

In phase 1, the initial vaccination is administered on or after 2 months of age, followed by three doses of either the DPT-IPV-Hib, DPT-IPV, or DPT vaccine, each given at intervals of at least 20 days, typically within a range of 20 to 56 days. If the DT vaccine is used, it is to be delivered in two doses no earlier than 3 months after birth. The phase 1 booster is administered at least 6 months after completion of the initial vaccination series–typically 6 to 18 months for DPT-IPV-Hib, and 12 to 18 months for DPT-IPV. Take care not to miss a vaccination, as multiple injections are required. Phase 2 administration is given once as a routine vaccination at the age of 11-12 years using DT. In principle, the same type of vaccine used for the initial dose should be used to complete the phase 1 vaccination series. However, if the mayor of the municipality acknowledges unavoidable circumstances, it is permissible to select a different type of vaccine.

Although it is a voluntary vaccination, your child may also receive the DPT vaccine during phase 2 to further strengthen immunity against pertussis.

To acquire sufficient immunity, your child must be vaccinated according to fixed intervals. However, even in the event the interval between injections becomes longer than that specified,

there are several methods which can be taken, so please consult with your family doctor or the municipal office.

The DPT-IPV-Hib and DPT-IPV can be used even with children who have already contracted one or more of pertussis, diphtheria, poliomyelitis (acute poliomyelitis), or tetanus.

In November 2012, the DPT (diphtheria, pertussis, tetanus) and IPV (inactivated polio) 4-in-1 vaccine Quattrovac® (manufactured by KM Biologics, with the last lot expiring June 5, 2025) and Tetrabik® (manufactured by the Research Foundation for Microbial Diseases of Osaka University) were introduced to the market. In December 2015, the DPT-IPV 4-in-1 vaccine, Squarekids® subcutaneous injection syringe (manufactured by Daiichi Sankyo Vaccine Co., Ltd.), was introduced to the market. However, the marketing of Squarekids® subcutaneous injection syringe (Daiichi Sankyo Vaccine Co., Ltd.) was discontinued in March 2021. Quintovac® (manufactured by KM Biologics Co., Ltd.) and GOBIK® (manufactured by the Research Foundation for Microbial Diseases of Osaka University) are 5-in-1 vaccines that have been included in Japan's routine immunization program since April 2024.

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0018% for the DPT-IPV-Hib vaccine, 0.0012% for the DPT-IPV vaccine, 0.0016% for the DPT vaccine, and 0.0002% for the DT vaccine. (The incidence reported from April 1, 2013 to September 30, 2024; for the 5-in-one vaccine, from the marketing launch in March 2024 to September 30, 2024. Source: January 2025 documents 2-17-1, 2-16, 2-11 and 2-12 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

Even in the absence of a serious adverse reaction, if your child is cranky or swelling occurs, consult with a doctor.

Although the incidence of diphtheria, pertussis, tetanus, and polio (acute poliomyelitis) has decreased, these diseases are all associated with serious complications, disabling sequelae, or even death. Therefore, it is recommended to receive vaccination for their prevention.

(3) Polio vaccine (inactivated vaccine)

An oral polio vaccine (OPV) had been used to eradicate polio in Japan and this state had been maintained up until August 2012; however, the OPV was replaced with an inactivated poliovirus vaccine (IPV) as a routine vaccination on September 1, 2012 in order to avoid vaccine-associated paralytic poliomyelitis (VAPP), a rare but serious adverse reaction to the OPV which develops in about one out of one million vaccine recipients. Since September 2012, the standalone inactivated poliovirus vaccine IMOVAX POLIO® subcutaneous (manufactured

by Sanofi) has been utilized. In November 2012, the 4-in-1 vaccine DPT-IPV, which combines vaccines for diphtheria, pertussis, tetanus, and inactivated polio (manufactured by KM Biologics Co., Ltd. and the Research Foundation for Microbial Diseases of Osaka University), was introduced. Furthermore, since April 2024, the 5-in-1 vaccine DPT-IPV-Hib, which adds protection against Haemophilus influenzae type b (Hib) to the aforementioned combination (also manufactured by KM Biologics Co., Ltd. and the Research Foundation for Microbial Diseases of Osaka University), has been in use.

The IPV includes antigens of three types of polio viruses (I, II and III). Resistance (immunity) to these three types of polio viruses reaches almost 100% with three IPV vaccinations; however, the fourth vaccination is needed because IPV maintains immunocompetence for a shorter time than the OPV.

A domestic clinical trial of IMOVAX POLIO® subcutaneous showed that pain (18.9%), erythema (77.0%), swelling (54.1%), fever of 37.5°C or more (33.8%), drowsiness (35.1%), and irritability (41.9%) were observed after the third vaccination. Precautions of shock and anaphylaxis (frequency unknown) and against convulsions as they were observed in 1.4% are described in the package insert. (See package insert [3rd ver.] revised in April 2023).

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0010%. (The incidence reported from April 1, 2013 to September 30, 2024. Source: January 2025 documents 2-15 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

The switch from OPV to IPV is taking place all over the world. However, there are many cases that OPV-derived viruses (circulating vaccine-derived poliovirus: cVDPV) still lurking in sewage and river water infect non-vaccinated individuals and cause paralysis in regions where vaccination rates are low. As cases of cVDPV infection have recently been reported in the United States, Israel, the United Kingdom, and Indonesia, there is a need to improve polio vaccination coverage in these countries. In Japan, the DPT-IPV vaccination rate is high, and cVDPV has not been detected, so the risk is extremely low. However, there is a possibility that the virus will be brought into Japan from overseas, so it is recommended to receive a vaccine containing IPV.

(4) Hib vaccine

Vaccination against Hib infection is basically provided with the 5-in-1 DPT-IPV-Hib combination vaccine. In cases where the Hib vaccine is used, the following procedures are followed according to the age in months at the time of initial vaccination. The standard vaccination procedure is as described in a) below:

a) A child aged 2 to 7 months (not exceeding the first day of 7 months) at the time of initiating the initial vaccination

The initial vaccination is conducted using a Hib vaccine provided three times at intervals of 27 days or more (20 days if required by a physician), with the standard interval being 27 (20 if required by a physician) to 56 days. The booster is conducted once at an interval of 7 months or more (usually 7 to 13 months) after the initial vaccination. It should be noted that the second and third injections of the initial vaccination are to be given by the time the child is 12 months of age, and are not to be given if the child exceeds 12 months. One booster may be given after an interval of at least 27 days (20 days if required by a physician) after the last vaccination of phase 1.

b) A child aged 7 months (the second day of 7 months) to 12 months (not exceeding the first day of 12 months) at the initiation of the initial vaccination

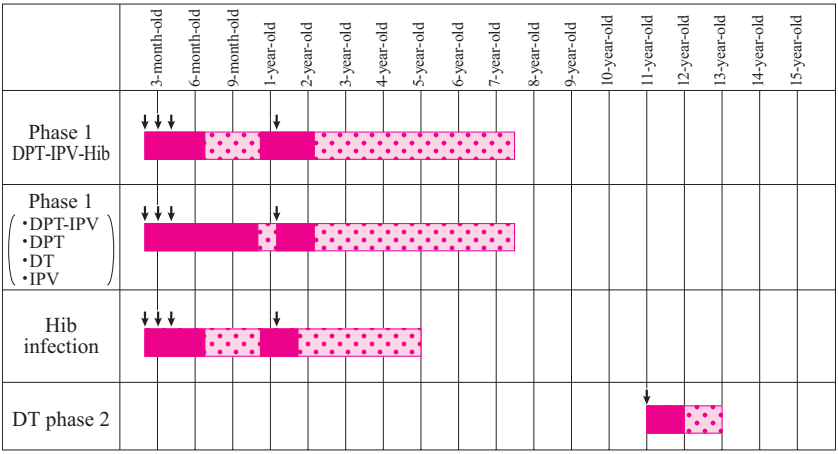
The initial vaccination is conducted using a Hib vaccine provided two times at intervals of 27 days or more (20 days if required by a physician), with the standard interval being 27 (20 if required by a physician) to 56 days. The booster is conducted once at an interval of 7 months or more (usually 7 to 13 months) after the initial vaccination. It should be noted that the second injection of the initial vaccination is to be given by the time the child is 12 months of age, and is not to be given if the child exceeds 12 months. One booster may be given after an interval of at least 27 days (20 days if required by a physician) after the last vaccination of phase 1.

c) A child aged 12 months (the second day of 12 months) to 60 months (not exceeding the first day of 60 months) at the initiation of the initial vaccination.

The vaccination is conducted using a Hib vaccine provided once.

A child who could not be vaccinated due to disease requiring long-term care is also vaccinated in this manner.

(5) Vaccination schedule



・The DPT-IPV-Hib, DPT-IPV, DPT, and DT can also be given to children who have already experienced pertussis.
If DT is used, it is to be delivered in two doses with the initial injection given no earlier than 3 months after birth.
The DPT-IPV-Hib, DPT-IPV, DPT, and DT can also be given to children who have already experienced any of the diseases of diphtheria, tetanus, or polio.
・In the phase 1 initial vaccination, the same type of vaccine is usually given the required number of times.
・When using the 5-in-1 vaccine in phase 1, refer to the top row.

◆ Tuberculosis

(1) Cause and course

Tuberculosis is caused by infection from Mycobacterium tuberculosis. The number of tuberculosis patients has markedly decreased in Japan, and the number of new cases in 2023 was 8.1 cases/100,000 population, falling below the WHO standard for low tuberculosis incidence (100 cases/100,000 population). However, tuberculosis can be transmitted to children from adults. Immunity against tuberculosis cannot be acquired in the womb, so newborn babies are also at risk of contracting the disease. Infants and children have low immunity against tuberculosis; as a result, they sometimes contract systemic tuberculosis or tuberculous meningitis, resulting in severe secondary complications.

It is recommended to receive a BCG vaccination within 1 year after birth as the BCG vaccine has the effect of preventing serious tuberculosis, such as meningitis and miliary tuberculosis, in infants.

The standard vaccination period is from 5 to 8 months after birth.

(2) BCG vaccine (live vaccine)

The BCG vaccine is made from attenuated Mycobacterium bovis.

The method used to administer the BCG vaccination in Japan is a percutaneous injection

using a specific multiple-puncture device, called the stamping method, that is pressed into two locations on the upper arm. The vaccine should not be given elsewhere on the body due to possible adverse reactions, including keloid formation. The vaccination site should be allowed to dry away from light for about 10 minutes.

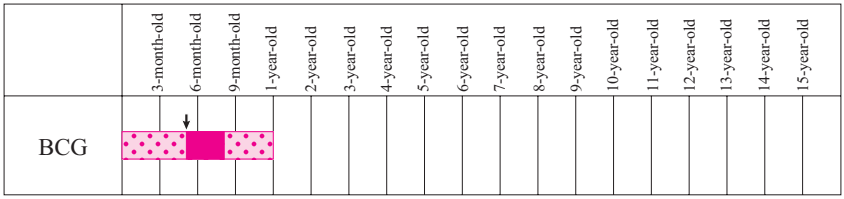
Red pockmarks appear on the vaccination site around 10 days after vaccination, and some may discharge a small amount of pus (fester). This reaction peaks about 4 weeks after vaccination; subsequently, the pockmarks are covered with scabs and heal completely by three months after vaccination, leaving only tiny scars. This scarring is not an abnormal reaction but evidence that a person has acquired immunity through the BCG vaccination. As the vaccination site will heal naturally, keep it clean and do not cover it with a bandage or plaster. However, if the vaccination site is still oozing three months after vaccination, please consult a doctor.

One rare adverse reaction is swelling in the lymph nodes below the armpit on the same side as the vaccination. This reaction can generally be left untreated; however, occasionally the area can become eroded, severely swollen, or, rarely, may fester and naturally tear. Should such a reaction occur, please consult a doctor.

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0026%. (The incidence reported from April 1, 2013 to September 30, 2024. Source: January 2025 documents 2-22 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

In cases where a child is infected with tuberculosis due to transmission from a family member etc., within 10 days (usually within 3 days) of the injection the vaccination site may show an inflammatory reaction called Koch's phenomenon (redness, swelling, and suppuration at the vaccination site, generally followed in 2 to 4 weeks by decreased redness, swelling, and inflammation, after which the wound scarifies [leaves a scar] and heals). Unlike the usual reaction time (generally about 10 days after vaccination), the Koch's phenomenon appears at an early stage, within several days of vaccination. If your child develops a reaction which suggests the Koch's phenomenon, promptly consult your municipality or a physician, as your child may require treatment. In such cases, family members and other individuals close to the child who may have transmitted tuberculosis will also require a medical examination.

(3) Vaccination schedule



◆ Measles and rubella

(1) Cause and course

a) Measles

Measles is caused by infection by the measles virus. Measles is highly contagious and spreads not only through droplets and contact but also through airborne transmission. Without vaccination, many people will contract the disease and there is risk of an epidemic. The main symptoms of prototypical measles are high fever, cough, runny nose, bloodshot eyes, eye discharge, and rash. For the first 3 to 4 days, patients have a fever of 38°C, which appears to decline but increases again to 39°C to 40°C, with a rash over the entire body. The fever goes down within 3 to 4 days, and the rash gradually disappears. The parts affected by the rash may remain darker for a while.

The main complications are bronchitis, pneumonia, otitis media, and encephalitis. About 7 to 9 out of 100 people with measles also get otitis media and about 1 to 6 get pneumonia. 1 to 2 out of 1,000 experiences encephalitis. One or two out of 100,000 measles patients develop subacute sclerosing panencephalitis (SSPE), a chronic progressive form of encephalitis. Reports indicate that the incidence is higher when the infection occurs in children under five years of age.

Measles is a severe disease; even in advanced countries with sophisticated medical care, around 1 out of 1,000 measles patients dies. In Japan, approximately 20 to 30 people died annually during the epidemic which occurred in the years around 2000. Globally, cases of measles are once again on the rise, and many children, primarily in developing countries, die from measles.

● Airborne infection (droplet nuclei infection)

With an airborne infection, the virus or bacterium is discharged into the air and infects people in open spaces. Measles, varicella (chicken-pox), and tuberculosis are airborne diseases.

b) Rubella

Rubella is caused by the rubella virus and is spread by droplet and contact transmission. The incubation period is 2 to 3 weeks. Prototypical rubella develops with mild cold-like symptoms, and the main symptoms are rash, fever, and posterior cervical lymphadenopathy (lymph nodes swelling in the back of the throat). Conjunctival congestion also occurs. Older children and adults experience a high frequency of arthritis. The prognosis is generally good, but thrombocytopenic purpura and encephalitis may also be observed, and, rarely, hemolytic anemia. According to the National Epidemiological Surveillance of Infectious Diseases, during the rubella outbreak from 2018 to 2019 (with a total of 5,239 cases), there were 21 reported cases of thrombocytopenic purpura and 2 reported cases of encephalitis. Adult patients experience severe symptoms.

When a pregnant woman is infected by the rubella virus before around the 20th week of pregnancy, there is a high risk of her infant being born with congenital rubella syndrome which may include heart abnormalities, cataracts, hearing impairment, and delayed growth and development.

(2) Combined measles-rubella (MR) vaccine, measles (M) vaccine, rubella (R) vaccine (live vaccine)

The MR live vaccine contains attenuated measles and rubella viruses.

Once your child turns 1 year old, you should have him or her receive the phase 1 vaccination as soon as possible.

Both the measles and rubella vaccines give 95% or more of children immunity after one injection, but as a precaution in case of non-response to the first dose and to prevent age-related decline of immunity, a second injection (phase 2 vaccination) is now performed.

Even if your child received an emergency measles and rubella vaccination before his or her first birthday, it is not counted in the number of vaccinations received because vaccination under one year of age is insufficient for acquiring immunity. Have him or her receive the routine phase 1 vaccination once he or she turns 1 year old, and the phase 2 vaccination once the appropriate age is reached.

Eligibility for the phase 2 vaccination is the year before admission into elementary school, that is, children in their final year of kindergarten or nursery school.

For the phase 1 and 2 vaccinations, the combined measles-rubella (MR) vaccine is used.

The combined measles-rubella (MR) vaccine can also be used for individuals who have already contracted measles or rubella.

If your child has received a gamma globulin injection for the purpose of treating or preventing illness, please consult your physician for the appropriate timing of vaccination.

The data concerning adverse reactions to the measles and the rubella vaccines shows that

anaphylaxis, thrombocytopenic purpura, encephalitis, and seizure may occur rarely.

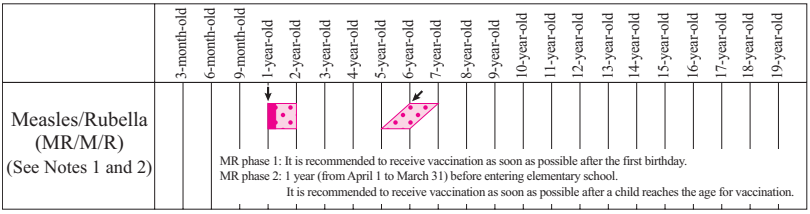
Febrile seizures (seizures caused by a fever) have occasionally (about 1 out of 300) been reported after measles vaccination. In addition, there have been reports of children experiencing encephalitis/encephalopathy in extremely rare cases (no more than 1 in 1 to 1.5 million children).

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0010%. (The incidence reported from April 1, 2013 to September 30, 2024. Source: January 2025 documents 2-1 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

Although the rubella vaccine is a live vaccine and the rubella virus multiplies in the body similarly to the measles vaccine, a vaccinated person does not infect those around him or her.

Measles causes severe symptoms and may result in sequelae or death. When a pregnant woman contracts rubella, her infant may be born with congenital rubella syndrome which may include heart abnormalities, cataracts, retinopathy, hearing impairment, and intelligence impairment. Make sure you are vaccinated so as to prevent contracting these diseases or transmitting them to others.

(3) Vaccination schedule



Note 1: A simultaneous vaccination for measles and rubella in phases 1 and 2 is given using the combined measles-rubella (MR) vaccine.

Note 2: Individuals with a confirmed history of either measles or rubella may receive either the vaccine for the disease they have not contracted or the combined measles-rubella (MR) vaccine; however, the MR vaccine is typically administered.

◆ Varicella (chickenpox)

(1) Cause and course

Varicella (chickenpox) is an acute infectious disease caused by initial infection with the varicella-zoster virus (hereinafter referred to as VZV). It is one of the most infectious diseases, spread by direct contact, droplets, and airborne infection. Once a person is infected, the virus remains latent in the body (in the trigeminal ganglia and other cerebral ganglia, and in the dorsal root ganglia) and reactivates to cause herpes zoster (shingles) when the person ages, or when the immune system is compromised.

The incubation period of varicella (chickenpox) is generally about 2-3 weeks (10-21 days). The main symptom of prototypical varicella (chickenpox) is a characteristic rash with itching. There may also be a fever. The rash begins as spotted red papules, progressing in 3 or 4 days to blisters that crust over and form scabs before healing. Although the rash tends to be distributed on the abdomen, back, and face, it also characteristically appears on the scalp and other parts which are covered with hair.

Varicella usually clears spontaneously in about 1 week, but in rare cases it can be accompanied by encephalitis, pneumonia, or liver function abnormality. Antiviral medication (e.g. Acyclovir) is sometimes used. It is not unusual for bacterial infections to develop via the skin and lead to purulence. In some cases, complications such as sepsis and other severe bacterial infections may occur. High-risk patients (patients with malignant tumors such as acute leukemia or patients who are or may be immunosuppressed due to treatment) are particularly likely to develop severe symptoms.

In accordance with regulations such as the Enforcement Regulations for the School Health and Safety Act, children are to refrain from attending nursery school, kindergarten, or elementary/middle/high school until all of the rash has crusted over (formed scabs).

When adults develop varicella (chickenpox), symptoms become more severe compared to children.

(2) Varicella (chickenpox) vaccine (live vaccine)

This is a live vaccine containing attenuated VZV.It was developed in Japan ahead of the rest of the world. About 20% of the individuals who receive this vaccine once experience varicella (chickenpox) later, but in a milder form. The vaccine is given twice to ensure that infection does not occur.

It has been shown that vaccine administration within 3 days of exposure to a varicella patient is effective in preventing disease. This kind of vaccination is also used to prevent hospital-acquired infection.

Almost no adverse reactions are observed in healthy children and adults; however, fever and rash occasionally develop, and local redness, swelling (puffiness), and induration (stiffness) are observed in rare cases. High-risk patients (patients who may be immunosuppressed due

to the effects of treatment for acute lymphatic leukemia or nephrotic syndrome) may receive the vaccination, provided that certain conditions are met. However, the patient may develop a fever with papules and blisters 14 to 30 days after vaccination. (See package insert [4th ver.] revised in June 2024)

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0010%. (The incidence reported from April 1, 2013 to September 30, 2024. Source: January 2025 documents 2-5 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

After being made a routine vaccination on October 2014, the incidence of varicella (chickenpox) decreased dramatically. The varicella vaccine can be given at the same time as the MR vaccine. Children aged 12 months to no later than 36 months are given a freeze-dried live attenuated varicella vaccine, with the first injection given when the child is 12 months to no later than 15 months as the standard vadcination period, and the second injection given after an interval of at least 3 months with the standard interval being between 6 to 12 months. Children with a history of varicella are not eligible for routine vaccination. Children who already received the varicella vaccine as a voluntary vaccination are deemed to have received the number of injections he or she has already undergone.

(3) Vaccination schedule

◆ Japanese encephalitis

(1) Cause and course

Japanese encephalitis is caused by the Japanese encephalitis virus. The Japanese encephalitis virus is transmitted by mosquitoes carrying viruses that have multiplied in pigs and other hosts. After an incubation period of 7 to 10 days, it may develop into acute encephalitis with symptoms such as high fever, headache, vomiting, disturbance of consciousness, and convulsions. Japanese encephalitis does not spread from person to person.

One in 100-1,000 people infected with the virus develops encephalitis, etc. Some people develop meningitis, while others may only experience symptoms like a summer cold. The fatality rate of encephalitis is about 20-40%, but many people suffer from nervous system sequelae after recovering from the disease.

In Japan, the disease occurs mainly in the western areas, but the Japanese encephalitis virus is

found throughout the nation and especially in western Japan. Japanese encephalitis outbreaks among domesticated pigs occur yearly from June to around October, during which time approximately 80% of pigs are infected in some geographical areas. In the past, the disease was prevalent among small and school-age children, but due to the wider use of vaccination and changes in living environments, the number of patients has decreased. In recent years, patients have mostly been elderly, but in 2015, a 10-months old infant in Chiba prefecture was determined to have Japanese encephalitis. There were also 11 reported incidents in 2016, mostly in elderly people. This was the first time the number of patients exceeded 10 per year since 1992. As of November 27, 2024, 8 incidents have been reported. (National Institute of Infectious Diseases [currently Japan Institute for Health Security], Infectious Disease Weekly Report (IDWR) 47th week 2024)

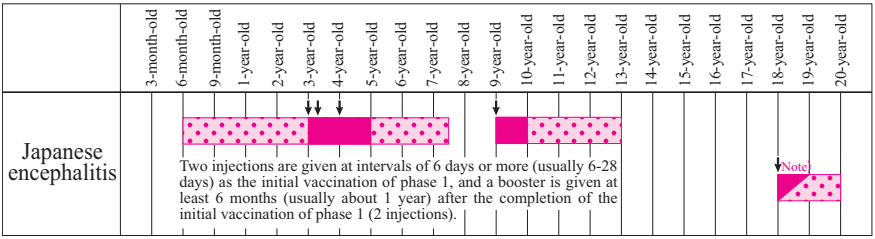
(2) Freeze-dried Japanese encephalitis vaccine (inactivated vaccine)

The freeze-dried cell culture-derived Japanese encephalitis vaccine in use in Japan today is created by growing the virus in Vero cells and killing (inactivating) the virus with a substance such as formalin, after which it is refined.

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0007%. (The incidence reported from April 1, 2013 to September 30, 2024. Source: January 2025 documents 2-23 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

Eligibility for the phase 1 routine vaccination is children between 6 and 90 months after birth. The standard schedule is to give two injections separated by an interval of 6 to 28 days from the day the child turns 3 and before his or her fourth birthday, and one injection from the fourth birthday to before the child turns 5. Eligibility for the phase 2 routine vaccination is children from 9 years to before he or she turns 13. The standard schedule is to give one injection between the child's ninth and tenth birthdays.

(3) Vaccination schedule



Note: Persons born between April 2, 1995 and April 1, 2007 who were unable to receive the phase 1 or 2 vaccines are able to receive the missed doses as routine vaccinations, if they are under the age of 20.

(4) Special consideration for vaccination (to secure opportunities for vaccination for children who were unable to receive the vaccine due to suspension of active recommendation in 2005)

Persons under the age of 20 who were born between April 2, 1995 and April 1, 2007 and who may not have received the phase 1 (three injections) and phase 2 (one injection) vaccine due to suspension of active recommendation on May 30, 2005 are eligible for the following measures to secure opportunities for vaccination.

a) Persons who are to receive 3 injections remaining of phase 1 and 2 (persons who received 1 injection of the initial vaccination in phase 1 [persons who received the first injection]) are to be given 2 injections of freeze-dried cell culture-derived Japanese encephalitis vaccine separated by an interval of at least 6 days, with the fourth injection for persons at least 9 years of age to be given after an interval of at least 6 days following the third injection.

b) Persons who are to receive 2 injections remaining of phase 1 and 2 (persons who received two injections of the initial vaccination in phase 1 [persons who received the second injection]) are to be given the third injection of freeze-dried cell culture-derived Japanese encephalitis vaccine after an interval of at least 6 days, with the fourth injection for persons at least 9 years of age to be given after an interval of at least 6 days following the third injection.

c) Persons who are to receive phase 2 of the vaccination (persons who have completed phase 1 injections [persons who received the third injection]) are to be given the fourth injection of freeze-dried cell culture-derived Japanese encephalitis vaccine, for persons at least 9 years of age after an interval of at least 6 days following the third injection.

d) Persons who have not received any of the phase 1 and 2 vaccinations are to be given freeze-dried cell culture-derived Japanese encephalitis vaccine with two (i.e., first and second) injections separated by an interval of at least 6 days (usually 6 to 28 days), followed by 1 booster at least 6 months (usually about 1 year) after the second injection (i.e., third injection), with the fourth injection for persons at least 9 years of age to be given with one injection after an interval of at least 6 days after the third injection.

In principle, vaccination should not be administered to women aged 13 or older if they are pregnant or possibly pregnant, and may be given only if the benefits are confirmed to outweigh the risks.

You can ask questions on vaccination and receive latest information from your municipality. A Q&A is available from the website of the Ministry of Health, Labour and Welfare: “Q&A

on Japanese encephalitis vaccination" (Japanese) (https://www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou21/dl/nouen_qa.pdf).

◆Human papillomavirus infection (protection against cervical cancer)

(1) Cause and course

The human papillomavirus (HPV) is a common virus which infects many people, of whom some women develop cervical cancer. Out of more than 100 genotypes of HPV, types 16 and 18 are considered to cause approximately 50 to 70% of cases of cervical cancer. Most HPV infections clear spontaneously and the virus becomes undetectable. However, in some women, over the course of several years to several decades, precancerous lesions and then cervical cancer will develop. Every year, 10,000 or more women develop cervical cancer in Japan, and an estimated 3,000 die from the disease (source: "Cancer Information Service," Center for Cancer Control and Information Services, National Cancer Center). In addition to vaccines to prevent HPV infection, early detection and early treatment of precancerous lesions through cervical cancer screening tests hold promise for decreasing incidence and mortality rates of this disease.

(2) HPV vaccine

Vaccines to prevent cervical cancer that are available as routine vaccinations in Japan are a bivalent vaccine (Cervarix®) containing antigens of the HPV type 16 and 18 viruses, which are most frequently detected from domestic and foreign patients with cervical cancer, and a tetravalent vaccine (Gardasil®) containing antigens of the type 6 and 11 viruses which cause condyloma acuminatum and recurrent respiratory papillomatosis. A 9-valent vaccine (Silgard® 9) which also protects against types 31, 33, 45, 52, and 58 was also approved and in April 2023 was included in the routine vaccination program. In foreign studies of persons not infected with HPV, each vaccine has been shown to be highly effective in preventing both infection and precancerous lesions. Therefore, countries are recommending that the vaccination be given to young people before their first sexual contact.

Adverse reactions described in domestic package inserts include local reactions such as pain (83-98%), redness (30-85%) and swelling (25-81%) at the injection site; and systemic reactions including slight fever (3-6%) and malaise; however, most of these are transient and disappear. (see the following package inserts: Cervarix® [1st ver.] revised in December 2023; Gardasil® [4th ver.] revised in January 2025; Silgard® 9 [2nd ver.] revised in January 2025).

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.0078% for Cervarix®, 0.0054% for Gardasil®, and 0.0012% for Silgard® 9. (The incidence reported from the market launch to September 30, 2024. Source: January 2025 documents 2-8, 2-9, 2-10 from the 105th Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

Vaccinated persons still need routine cervical cancer screening because the vaccine may not always provide sufficient immunization or does not protect against HPV types which are not contained in the vaccine, causing cervical cancer.

a) When using the bivalent vaccine for the prevention of human papillomavirus infection, the standard vaccination period is from the first day to the last day of the fiscal year in which the individual turns 13. The standard schedule is to give 2 injections separated by an interval of 1 month, followed by another injection after an interval of at least 6 months after the first injection. If said schedule cannot be followed, 2 injections are given separated by an interval of at least 1 month, followed by 1 injection after an interval of at least 5 months after the first injection, and 2.5 months after the second injection.

b) When using the tetravalent vaccine for the prevention of human papillomavirus infection, the standard vaccination period is from the first day to the last day of the fiscal year in which the individual turns 13. The standard schedule is to give 2 injections separated by an interval of 2 months, followed by another injection after an interval of at least 6 months after the first injection. If said schedule cannot be followed, 2 injections are given separated by an interval of at least 1 month, followed by 1 injection after an interval of at least 3 months after the second injection.

c) When using the 9-valent vaccine for the prevention of human papillomavirus infection, the standard vaccination period is from the first day to the last day of the fiscal year in which the individual turns 13. One of the two schedules shown below is to be followed (the schedule shown in i) is to be followed only when giving the vaccine to an individual between the first day of the fiscal year in which the individual turns 12 and the date the individual turns 15 at the time of the first injection).

    i) The standard schedule is to give 2 injections separated by an interval of 6 months. If said schedule cannot be followed, 2 injections are given separated by an interval of at least 5 months.

    ii) The standard schedule is to give 2 injections separated by an interval of 2 months,

followed by another injection after an interval of at least 6 months after the first injection. If said schedule cannot be followed, 2 injections are given separated by an interval of at least 1 month, followed by 1 injection after an interval of at least 3 months after the second injection.

d) In general, the same human papillomavirus vaccine formulation should be used to complete the series, if possible. However, in light of a certain level of evidence indicating the safety and immunogenicity of the bivalent, quadrivalent, or 9-valent vaccine administered to the same individual, municipalities may, if the mayor recognizes that there are unavoidable circumstances preventing the use of the methods listed in a) or b), conduct the rest of the series following one of the two schedules shown below for individuals who have been given the bivalent or quadrivalent vaccine for their first or second injections.

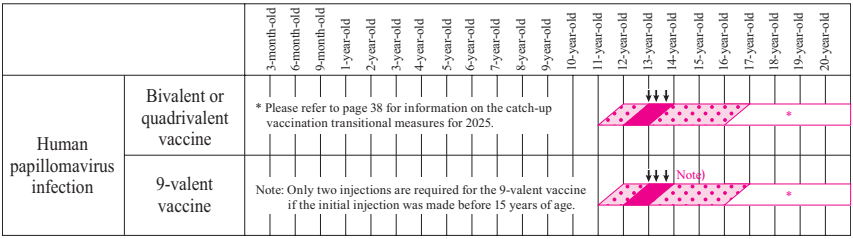
   i) An individual given the bivalent or quadrivalent vaccine for their first injection is given 1 intramuscular injection of the 9-valent vaccine after an interval of 2 months from the first injection, followed by 1 injection of the same vaccine after an interval of 6 months from the first injection. However, if said schedule cannot be followed, the individual is given 1 intramuscular injection of the 9-valent vaccine after an interval of 1 month from the first injection, followed by another injection given intramuscularly using the same vaccine after an interval of at least 3 months from the second injection.

   ii) An individual given the bivalent or quadrivalent vaccine for their first and second injections is given 1 intramuscular injection of the 9-valent vaccine after an interval of 6 months from the first injection. However, if said schedule cannot be followed, the individual is given 1 intramuscular injection of the 9-valent vaccine after an interval of at least 3 months from the second injection.

e) If the type of human papillomavirus-like particle vaccine given in the past is unknown, the choice of which vaccine to give should be made upon consultation between the vaccine recipient and the doctor of the medical institution conducting the vaccination.

f) Syncope, a vasovagal reaction, sometimes occurs after vaccination against human papillomavirus infection. Therefore, to prevent falls or other accidents due to syncope, children who have been vaccinated should be accompanied and supported by their parent/guardian or healthcare professional when moving after the injection. After injection, they should be seated in a place where they can safely rest their weight, instructed not to stand as much as possible, and observed for 30 minutes after injection.

(3) Vaccination schedule



(4) Routine HPV vaccination

At the June 14, 2013 joint meeting of Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Science Council and the Subcommittee on Drug Safety of the Committee on Drug Safety in the Pharmaceutical Affairs and Food Sanitation Council, it was set forth that "due to sustained pain whose relationship with the vaccine cannot be ruled out being observed after vaccination with the HPV vaccine, the routine vaccination should not be actively recommended until the frequency of onset of this adverse reaction is further elucidated and appropriate information can be provided to citizens," and the decision was made by the Ministry of Health, Labour and Welfare to suspend active recommendation of the vaccination. After that, since November 2021, at the same meeting, it has been discussed how to evaluate the efficacy and safety of HPV vaccines, how to deal with the symptoms that occur after HPV vaccination, and how to provide information about HPV vaccines. In conclusion, it was confirmed that there were no particular concerns about safety, and that the efficacy of vaccination clearly outweighed the risk of adverse reactions. Then, in November 2021, a notice was issued to end "the suspension of active recommendation." In December 2021, a notice was issued stating that vaccination shall be provided temporally beyond the target age of conventional routine vaccinations (hereinafter referred to as "catch-up vaccinations") as a measure for those who missed the opportunity of vaccination due to the suspension of active recommendation. The Preventive Vaccination Law Enforcement Ordinance (Cabinet Order No. 197 of 1948) was revised and came into effect on April 1, 2022.

To ensure fair vaccination opportunities for those who missed the vaccination opportunity due to the suspension of active recommendation, a temporary program was implemented from fiscal year 2022 until March 31, 2025. This program provided vaccinations beyond the conventional routine vaccination age to females born between fiscal years 1997 and 2007.

Note that the WHO and the Japanese Medical Society have positioned the HPV vaccine

as a "vaccine necessary to protect women from cancer." In Japan, to prevent certain types of cancer in men, the indication for the quadrivalent HPV vaccine was extended to include males in December 2020, making it available as a voluntary vaccination for males aged 9 and older. Routine HPV vaccination for men is currently under review.

Transitional measures for catch-up vaccination in 2025

The catch-up vaccination period stipulated in the Preventive Vaccination Law Enforcement Ordinance was set from April 1, 2022, to March 31, 2025. However, considering the limited vaccine supply due to a significant increase in demand from the summer of 2024 onward, transitional measures have been established. The measures allow individuals who have received at least one dose during the catch-up period to complete the three-dose series at public expense even after the period ends.

<Eligibility>

- Women born between April 2, 1997 and April 1, 2009, who have received at least one dose of the HPV vaccine during the three-year period from April 1, 2022 to March 31, 2025

<Transitional measures period>

- From April 1, 2025 to March 31, 2026

For individuals who received one or two doses of the vaccine during the three-year period but were unable to follow the standard vaccination schedule due to unavoidable circumstances and had to interrupt their vaccination, it is permissible to complete the remaining doses (second and third doses, or just the third dose) without restarting the vaccination series from the beginning.

For more information on the safety and efficacy of the HPV vaccines, please refer to the brochure on the HPV vaccines posted on the Ministry of Health, Labour and Welfare website (https://www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou28/index.html). For details on the HPV catch-up vaccination transitional measures, please check the latest information from the Ministry of Health, Labour and Welfare and your municipality as corrections may be made.

8. What to do if your child experiences an adverse reaction to a vaccination

(1) Normally observed reactions

Depending on the type of vaccine, fever, redness, swelling (puffiness), and induration (stiffness), and rashes at the injection site occur fairly often (several percent to several tens of percent). In many cases, these symptoms disappear within several days and are not a cause for concern.

(2) Severe adverse reactions

If your child has severe swelling at the vaccination site, or has fever or seizures after vaccination, consult a doctor. If your child's symptoms meet the criteria for reporting adverse reactions after vaccination, the doctor will inform the Pharmaceuticals and Medical Devices Agency (PMDA).

Although adverse reactions depend on the type of vaccine, vaccination extremely rarely (about one in several million people) causes serious adverse reactions, such as encephalitis and neuropathy. Such cases will be evaluated on the basis of Japan's basic approach in regard to relief programs, namely that "rigorous medical causation is not imperative and that relief shall also apply in cases where the possibility of symptoms which appeared after vaccination having been caused by the vaccination cannot be ruled out." On this basis, the patient is considered eligible for compensation for the health damage under the Preventive Vaccination Law if the Minister of Health, Labour and Welfare gives authorization.

(3) Coincidental reactions

Symptoms that occur soon after vaccination are often thought to have been caused by vaccination. However, sometimes these symptoms are caused by another infection that happens to develop simultaneously. This is then called a "coincidental reaction."

(4) Relief system for people with health damage due to vaccination

a) A person who has an adverse reaction due to routine vaccination or provisional vaccination and whose ability to perform daily activities is impaired due to health damage can be compensated by the government according to the Preventive Vaccination Law.

b) The compensation consists of payment of medical expenses, medical benefits, an annuity for disabled children, a disability annuity, lump-sum death benefits, and funeral expenses, all of which are designated by law according to the severity of the health damage. All compensation, except lump-sum death benefits and funeral expenses, is continually paid until the completion of treatment or improvement in the impairment.

c) Compensation is paid to the patient after the relevant health damage has been certified to be caused by vaccination by a governmental review committee comprising specialists in vaccination, infection medicine, law, and related disciplines, who discuss the causal relationship of the relevant health damage with vaccination, i.e., whether it was caused by vaccination or other factors (infection before or after vaccination, or other causes).

d) When vaccination is desired after the designated period for routine or provisional vaccination, said vaccination is considered not to be controlled under the Preventive Vaccination Law (voluntary vaccination). In the event a child suffered health damage from such a vaccination, he/she will receive relief according to the Pharmaceuticals and Medical Devices Agency Law; however, the subject and the amount of compensation differ from those of the Preventive Vaccination Law.

* In the event you need to submit an application for compensation, consult with your municipal office in charge of vaccination.

* The following topics are quoted from the "Vaccination Guidelines 2025 Version" from the Public Foundation of Vaccination Research Center regarding COVID-19 vaccination.

[Reference 1] Novel coronavirus (COVID-19) infection

(1) Overview of the disease

An outbreak of unexplained pneumonia in Wuhan City, Hubei Province, China at the end of December 2019 was reported. On January 9, 2020 it was announced that the causative virus was a novel coronavirus. The international name of the disease was announced as COVID-19 and the causative virus was designated as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). With the virus expected to spread rapidly to other countries across the world, the World Health Organization (WHO) declared the situation a Public Health Emergency of International Concern (PHEIC) on January 30, 2020 and characterized the outbreak as a pandemic on March 11 of the same year.

In Japan, COVID-19 was specified on January 28, 2020 as a "Designated Infectious Disease" according to the Infectious Diseases Control Law. In terms of the School Health and Safety Act, it was deemed to be equivalent to Category 1 on the basis of the Infectious Diseases Control Law. On March 13, 2020, the Act on Special Measures against Novel Influenza, etc., was amended to stipulate that measures against COVID-19 would be taken on the basis of this Act. On December 9, 2020, COVID-19 became a target for provisional vaccination. Subsequently, Japan faced roughly 8 waves of outbreaks by May 2023. However, COVID-19 was classified as a Category 5 infectious disease under the Infectious Diseases Control Law and became subject to sentinel surveillance in the infectious diseases surveillance on May 8, 2023, when the eighth wave showed signs of decrease. Accordingly, it was classified as a Category 2 infectious disease under the School Health and Safety Act.

On May 5, 2023, the WHO declared that COVID-19 is no longer a PHEIC, although with a warning that it still remained a global threat.

Since the emergence of the Omicron strain, the incubation period has shortened to 2 or 3 days in most cases. The route of transmission is mainly by droplets, although aerosol transmission also occurs in closed spaces. Contact infection is possible but less frequent.

As it is a respiratory disease, the symptoms are mainly fever, sore throat, coughing, etc. When it first began to spread, pediatric cases were few and asymptomatic or mostly mild even in case of symptoms being present. However, infections in children have increased since the Omicron strain became predominant, with more cases developing complications of febrile seizures and

croup-like symptoms. Children under the age of 2 and persons with underlying conditions are considered at risk for severe disease. Rates of severe disease and death are high in the elderly.

(2) Effectiveness of vaccination

Vaccination has been shown to be effective in preventing the onset of disease and reducing the severity (including hospitalization) of COVID-19, as confirmed by numerous reports both domestically and internationally Furthermore, even individuals who have previously been infected with COVID-19 are at risk of reinfection. Studies have demonstrated that vaccination provides additional protective effects against the onset of disease in such cases. Furthermore, it has been observed across all age groups that the effectiveness of the vaccine in preventing severe disease (hospitalization) is higher than its effectiveness in preventing the onset of illness. Additionally, studies conducted overseas have reported that COVID-19 vaccination may help prevent Long COVID (post-acute sequelae of SARS-CoV-2 infection).

(3) Vaccine characteristics

Although COVID-19 vaccines were being developed in Japan and abroad, the first vaccine to be used for practical vaccination was an mRNA vaccine containing the mRNA of the SARS-CoV-2 spike protein encapsulated in lipid nanoparticles. Other vaccines in practical use include recombinant viral vector vaccines which use non-pathogenic viruses carrying SARS-CoV-2 spike protein, and live-attenuated vaccines. In Japan, the Pfizer mRNA vaccine was approved for marketing on February 14, 2021. Provisional vaccination under the Preventive Vaccination Law began on February 17, 2021 for healthcare personnel and on April 12, 2021 for the elderly. On May 21, 2021, the Takeda/Moderna mRNA vaccine and the AstraZeneca recombinant chimpanzee adenovirus vector vaccine were approved for marketing. At large-scale vaccination centers, vaccination using the Takeda/Moderna mRNA vaccine started on May 24, 2021 for the elderly, and workplace vaccinations started on June 21, 2021. Vaccination with the AstraZeneca recombinant chimpanzee adenovirus vector vaccine ended at the end of September 2022.

As of October 2024, COVID-19 has been designated a Category B infectious disease under the Preventive Vaccination Law. Consequently, routine vaccinations commenced targeting individuals aged 65 and older, as well as those aged 60–64 with specific underlying health conditions. These vaccinations are administered once annually during a period set by each municipality between October 1 and March 31. The antigen composition of the vaccine to be used for routine vaccination in the 2024/25 season has been proposed to be the monovalent

JN.1 strain (Second Meeting of the Health Science Council [Subcommittee on Vaccination and Vaccines, Subcommittee on Research, Development, Production, and Distribution, and Subcommittee on the Manufacturing Strains of Seasonal Influenza Vaccines and COVID-19 Vaccines: May 29, 2024]). Vaccination against COVID-19 using vaccines tailored to circulating variants is expected to elicit higher neutralizing antibody titers, thereby enhancing not only protection against severe disease but also improving the prevention of symptomatic infection. Based on these scientific findings, the Ministry of Health, Labour and Welfare has decided, following discussions in its advisory council, to review annually, for the time being, the type of COVID-19 vaccine (i.e., the strain included in the vaccine) used for routine immunization.

(4) Precautions for injection

As of the present, all of the COVID-19 vaccines are delivered intramuscularly. It is necessary to check the vaccine recipient's age against the vaccine type in advance of injection.

At the 55th Meeting of the Subcommittee on Vaccination and Vaccines of the Health Sciences Council in February 2024, approval was given for the simultaneous injection of COVID-19 vaccine and another vaccine without an interval requirement when deemed necessary by a physician after FY 2024. These measures are similar to those for other vaccines except injectable live vaccines.

Presently, individuals aged 65 and older, as well as those aged 60 to 64 with certain underlying health conditions, are eligible for routine vaccination.

(5) Adverse reactions

A variety of symptoms including injection site pain, malaise, headache, and fever have been identified, but most are mild to moderate. No significant safety concerns have been identified from the information obtained to date. There are also reports indicating that the incidence of adverse reactions is lower in younger people. In Japan, cases of myocarditis and pericarditis classified as Brighton Collaboration levels 1 to 3 have been reported, particularly among young males.In Japan, anaphylactic shock has been reported as a serious adverse reaction. Vaccine recipients should be remained at the site and observed for a minimum of 30 minutes after vaccination, and must seek medical attention in the event of symptoms such as chest pain, palpitations, shortness of breath, or edema within several days post-vaccination.

[Reference 2] Diseases preventable by voluntary vaccination and overview of vaccines

Voluntary vaccination, which is not subject to the Preventive Vaccination Law, is conducted in consultation between a vaccine recipient (parents/guardians) and a doctor and is not promoted by the government; however, the vaccines used are approved by the Ministry of Health, Labour and Welfare under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Pharmaceuticals and Medical Devices Act).

Voluntary vaccinations include vaccinations to prevent seasonal influenza (a routine vaccination for adults from 65 years), mumps, hepatitis A, yellow fever, rabies, tetanus, meningococcal infection, herpes zoster (shingles), RS virus infection, tick-borne encephalitis, typhoid fever, and Mpox, as well as routine vaccinations when they are given outside the eligible age range or period.

The seasonal influenza and mumps vaccines that many children receive are explained below.

In the unlikely event a child suffers health damage by a voluntary vaccination, he/she may be eligible for relief according to the Pharmaceuticals and Medical Devices Agency Law; However, the subject and the amount of compensation differ from those of the Preventive Vaccination Law (routine vaccination).

* In the event you need to submit an application for compensation, consult with your municipal office in charge of vaccination.

◇ Seasonal influenza vaccine (inactivated vaccine, live intranasal vaccine)

The seasonal influenza vaccination (inactivated vaccine) for the elderly is designated as a routine vaccination by the Preventive Vaccination Law Enforcement Ordinance; that for children is considered a voluntary vaccination.

(1) Cause and course

Seasonal influenza is an acute respiratory infection which suddenly develops systemic symptoms including fever, chills, headache, and muscle pain. The incubation period is 24-72 hours. Respiratory symptoms (stuffy nose, sore throat, and cough, etc.) often appear later. Patients without complications recover within 2-7 days. Complications, especially pneumonia and encephalopathy, are serious.

(2) Overview of vaccine

There are two types: one is an inactivated vaccine made by inoculating each of the 2 lineages of seasonal influenza type A (H1N1 and H3N2) and 2 of type B (Yamagata and Victoria) into the chorioallantoic membrane of embryonated chicken eggs, allowed to multiply,extracting the

hemagglutinines from the virus surface with ether, and inactivating it with formalin; the other is a live attenuated intranasal spray vaccine (containing two types of A viruses and one type of B virus [Victoria lineage]) for individuals aged 2 to under 19 years. There is no significant difference in the effectiveness of inactivated influenza vaccines and live intranasal vaccines, and both have no major issues concerning adverse reactions.Decisions are made each year on which viral strains to include in the seasonal influenza vaccine, on the basis of epidemiological and virological assessments.

Reports vary on the effectiveness of the influenza vaccine in infants and young children. In a 2015/16 season study in children under 6 years of age, the efficacy of the influenza vaccine in preventing disease was reported to be 60%. Influenza vaccines are considered to be effective to a certain extent in preventing the onset of disease as well as in preventing severe illness and death in the event symptoms develop. (Quoted from the Ministry of Health, Labour and Welfare website, Influenza Vaccine [Seasonal] Q&A [Q1].)

Embryonated chicken eggs are used in the manufacturing process of the seasonal influenza vaccine; however, the egg components are eliminated in the purification process. Nevertheless, caution is necessary when vaccinating persons with clear allergies to eggs. Persons who experience an anaphylactic reaction to chicken eggs and meat are asked to consult with a specialized facility if they wish to receive the vaccine.

The incidence of serious cases (cases deemed to be serious by the reporter) among suspected cases of adverse reactions (adverse events) reported by medical institutions was 0.00009%. (The incidence reported from October 1, 2023 to March 31, 2024. Source: July 2024 documents 2-29 from the 102nd Working Group Meeting on Adverse Events, the Subcommittee on Vaccination and Vaccines of the Health Sciences Council.)

◇ Mumps vaccine (live vaccine)

(1) Cause and course

Mumps is caused by the mumps virus and is spread by droplet or contact infection. The virus proliferates and spreads throughout the body, causing lesions in various internal organs. The incubation period is 2-3 weeks. The period which an infected person may infect those around them is believed to be from several days before onset to 5 days after start of swelling of the parotid gland, submaxillary gland, or sublingual gland. The primary symptom is swelling of the parotid gland, which exhibits indistinct borders and uniform, and is painful. The submaxillary gland and/or sublingual gland may also develop swelling, and may also be accompanied by fever.When older children or adults contract the disease, symptoms tend to be more pronounced, and the frequency of complications increases. The most common

complication is aseptic meningitis, with a reported diagnostic frequency ranging from 1% to 10%. Although rare, other complications include encephalitis and pancreatitis. In post-pubertal males, orchitis may occur, while in females, oophoritis may develop. Particular attention should be paid to the risk of mumps-related hearing loss, which can be difficult to treat.

(2) Overview of vaccine

This is a live vaccine containing attenuated mumps viruses. The post-vaccination seroconversion rate is high, at more than 90%, and in domestic outbreak investigation, the effect of the vaccine is believed to be about 80%. Most people who develop the disease despite being vaccinated generally experience a milder form of the disease. (Report by Mumps Vaccine Working Team of the Vaccination Working Group)

Possible adverse reactions to mumps vaccines available on the market include mild swelling of the parotid glands in around 1%. The frequency of the adverse reaction of aseptic meningitis is stated to be about 1 in every 1,600-2,300 persons vaccinated (from vaccine package insert); however, although it has recently been reported that there are differences in frequency depending on the age of vaccination, it has been reported that the frequency is even lower. Given the 1-10% incidence of the complication of aseptic meningitis in spontaneous infections; as well as the risk of hearing loss, the need for extended absence from nursery or elementary school when infected; and the high incidence in children aged 3-6; it is recommended that children be vaccinated at the same time as, or as soon as possible after, MR vaccine phase 1, the first varicella vaccine injection, the Hib vaccine booster, and the pediatric pneumococcal vaccine booster, etc., and at the very latest, no later than 3 years of age, which is the high incidence age. In addition, the Japan Pediatric Society recommends administering a second dose concurrently with phase 2 of the MR vaccine to ensure its preventive effectiveness.

Form 2

Vaccine Screening Questionnaire for [ ] (infant/schoolchild)

		Body temperature before interview		Degrees
Address				
Child's Name		M F	Birth date	/ / (YYYY/MM/DD) Age (years months)
Parent/Guardian's Name				

Questionnaire for Vaccination	Answer		Doctor's comment
Have you read the document (sent to you previously by the municipal office) explaining the vaccination that will be administered today?	Yes	No	
Please answer the following questions about the child. Birth Weight Did the child have any abnormal findings at delivery? ( ) g Did the child have any abnormal findings after birth? Was any abnormality identified at an infant health check?	Yes Yes Yes	No No No	
Is the child sick today? If so, describe the nature of the illness. ( )	Yes	No	
Has the child been ill in the past month? Disease name ( )	Yes	No	
Has any family member or friend of the child had measles, rubella, chickenpox or mumps in the past month? Disease name ( )	Yes	No	
Has the child been exposed to anyone with tuberculosis (including family members)?	Yes	No	
Has the child been vaccinated in the past month? Vaccine name ( )	Yes	No	
Does the child have a congenital anomaly, heart, kidney, liver, central nerve disease, immune deficiency, or any other diseases for which you have consulted a doctor? Disease name ( )	Yes	No	
Where relevant, did the doctor who manages the above disease agree with today's vaccination?	Yes	No	
Has the child had a seizure (spasm or fit) in the past? If so, at what age did it occur? ( )	Yes	No	
If you answered "yes" to the preceding question, did the child have a fever at that time?	Yes	No	
Has the child ever had a rash or urticaria (hives or 'nettle rash') as a reaction to medications or food or become ill after eating certain foods or receiving certain medications?	Yes	No	
Does the child have a family member or relative with a congenital immunodeficiency?	Yes	No	
Has the child become ill after receiving a vaccine in the past? Vaccine name ( )	Yes	No	
Has any family member or relative of the child become ill after receiving a vaccine in the past?	Yes	No	
Has the child received a transfusion of blood or blood products or been given a medicine called gamma globulin in the past 6 months?	Yes	No	
Do you have any questions about today's vaccination?	Yes	No	
Doctor's comment Based on the above answers and the results of interview, I have decided that the child (can / should not) receive a vaccination today. I have explained to the parent/guardian the information concerning the benefits and side effects of vaccination and the support provided to people who have had adverse events associated with vaccination. Signature or Name and Seal of Doctor:			

This screening questionnaire is used to improve the safety of vaccination. The child has been interviewed by the doctor, and information concerning the benefits, objectives, and risks (including serious side effects) of vaccination has been explained to me by the doctor, as has the nature of support provided if adverse events occur. I believe that I understand this information.

I (do / do not)* give consent for the child to be vaccinated. * Please circle your choice.

I understand the above and agree that this questionnaire can be submitted to the municipal office.

Signature of Parent / Guardian:

Vaccine Name	Dosage	Institution / Doctor Name / Date Administered
Vaccine Name Lot Number [Caution] Confirm that the expiration date of the vaccine is valid.	* Route / Method mL	Institution: Doctor Name: Date Administered: / / (YYYY/MM/DD)

[Note] Gamma globulin is a blood product that is injected to prevent infections, such as type A hepatitis, and to treat severe infections. Certain vaccines (for example, measles vaccine) are occasionally less effective in people who have received this product in the preceding 3 to 6 months.

* For BCG vaccination, enter "percutaneous injection at the prescribed dose using a BCG-specific multiple-puncture device," etc. For the 5-in-1 vaccine or the 15-valent pneumococcal conjugate vaccine, specify whether it is administered via "subcutaneous or intramuscular injection".

Form 8

Hepatitis B Vaccine Screening Questionnaire

		Body temperature before interview		Degrees
Address				
Child's Name		M F	Birth date	/ / (YYYY/MM/DD)
Parent/Guardian's Name				Age (years months)

Questionnaire for Vaccination	Answer		Doctor's comment
Have you read the document (sent to you previously by the municipal office) explaining the vaccination that will be administered today?	Yes	No	
Please answer the following questions about the child. Birth Weight ( ) g Did the child have any abnormal findings at delivery? Did the child have any abnormal findings after birth? Was any abnormality identified at an infant health check?	Yes Yes Yes	No No No	
Is the child sick today? If so, describe the nature of the illness. ( )	Yes	No	
Has the child been ill in the past month? Disease name ( )	Yes	No	
Has any family member or friend of the child had measles, rubella, chickenpox or mumps in the past month? Disease name ( )	Yes	No	
Has the child been vaccinated in the past month? Vaccine name ( )	Yes	No	
Does the child have a congenital anomaly, heart, kidney, liver, central nerve disease, immune deficiency, or any other diseases for which you have consulted a doctor? Disease name ( )	Yes	No	
Where relevant, did the doctor who manages the above disease agree with today's vaccination?	Yes	No	
Has the child had a seizure (spasm or fit) in the past? If so, at what age did it occur? ( )	Yes	No	
If you answered "yes" to the preceding question, did the child have a fever at that time?	Yes	No	
Has the child ever had a rash or urticaria (hives or 'nettle rash') as a reaction to medications or food or become ill after eating certain foods or receiving certain medications?	Yes	No	
Does the child have a family member or relative with a congenital immunodeficiency?	Yes	No	
Has the child become ill after receiving a vaccine in the past? Vaccine name ( )	Yes	No	
Has any family member or relative of the child become ill after receiving a vaccine in the past?	Yes	No	
Has the child received a transfusion of blood or blood products or been given a medicine called gamma globulin in the past 6 months?	Yes	No	
Did the child receive the hepatitis B vaccine after birth as part of the mother-to-infant transmission prevention program?	Yes	No	
Do you have any questions about today's vaccination?	Yes	No	
Doctor's comment Based on the above answers and the results of interview, I have decided that the child (can / should not) receive a vaccination today. I have explained to the parent/guardian the information concerning the benefits and side effects of vaccination and the support provided to people who have had adverse events associated with vaccination. Signature or Name and Seal of Doctor:			

This screening questionnaire is used to improve the safety of vaccination. The child has been interviewed by the doctor, and information concerning the benefits, objectives, and risks (including serious side effects) of vaccination has been explained to me by the doctor, as has the nature of support provided if adverse events occur. I believe that I understand this information.
I (do / do not)* give consent for the child to be vaccinated. * Please circle your choice.
I understand the above and agree that this questionnaire can be submitted to the municipal office.
Signature of Parent / Guardian:

Vaccine Name	Dosage	Institution / Doctor Name / Date Administered
Vaccine Name Lot Number [Caution] Confirm that the expiration date of the vaccine is valid.	* (Subcutaneous injection) mL	Institution: Doctor Name: Date Administered: / / (YYYY/MM/DD)

Form 9

Rotavirus Vaccine Screening Questionnaire

Parent/guardian: Please fill out the bolded fields.

			Date	/ / (YYYY/MM/DD)
Address			**Pre-exam temperature**	degrees (include decimal)
			Phone no.	– –
Child's name		**M / F**	**Child's date of birth**	/ / (YYYY/MM/DD)
Parent/guardian's name				(Age: weeks days)
				For age in weeks and days, count the day after the date of birth as day 1.

If this is the first vaccination, have you confirmed that the child is not older than 14 weeks and 6 days as of today?	Field for medical institution to enter (Mark a ☑)

Questionnaire	**Answer**			**Doctor's comment**
Which vaccination will your child receive today?	1st	2nd	3rd	
Please write the date(s) of the vaccination(s) your child has received so far (answer only if this is your child's 2nd or 3rd vaccination). Note: Confirm that at least 27 days have passed since your child's last rotavirus vaccination.	1st / / (YYY/MM/DD) 2nd / / (YYY/MM/DD)			
Have you read the document provided by the municipal office explaining the vaccination that will be administered today?	Yes	No		
Do you understand the benefits and side effects of the vaccination that will be administered today?	Yes	No		
Were you provided with information concerning intussusception, and did you understand that information?	Yes	No		
The following questions concern your child's growth and development. Birth weight: g				
Were there any abnormalities at the time of delivery?	Yes	No		
Have there been any abnormalities after birth?	Yes	No		
Have any abnormalities been identified in an infant health exam?	Yes	No		
Is your child experiencing any illness or does your child feel unwell today? Please describe the symptoms:	Yes	No		
Has your child been sick within the last month? Name of illness:	Yes	No		
Has any family member or friend of the child had measles, rubella, chickenpox, or mumps in the past month? Name of illness:	Yes	No		
Has your child been vaccinated within the past month? Vaccine: Date: (YYYY/MM/DD)	Yes	No		
Has your child experienced intussusception before? Or does your child have an untreated congenital abnormality of the gastrointestinal tract? Note: If yes, your child cannot receive the rotavirus vaccine.	Yes	No		
Has your child been diagnosed with immunodeficiency? Or has your child experienced repeated diarrhea, repeated infections such as pneumonia or middle ear infections, or had difficulty gaining weight? Note: If yes, your child may not be able to receive the rotavirus vaccine.	Yes	No		
Does your child have a congenital anomaly; gastrointestinal disorder; heart, kidney, liver, blood, or central nervous disease; or any other diseases for which you have consulted a doctor? Name of illness:	Yes	No		
If you answered yes to the previous question, have you been told by the doctor whom your child is seeing for that disease that your child may receive today's vaccination?	Yes	No		
Has your child had a seizure (spasm or fit) in the past? If so, at around how many months of age: months	Yes	No		
If you answered yes to the previous question, did your child have a fever at that time?	Yes	No		
Has your child ever had a rash or hives or become ill after eating certain foods or receiving certain medications? If you answered yes to the previous question, name of medication/food:	Yes	No		
To date, has your child ever felt ill after receiving a vaccination? If you answered yes to the previous question, name of vaccine:	Yes	No		
Did the mother take medication which suppresses the immune system while pregnant with the child? If you answered yes to the previous question, name of medication:	Yes	No		
Has a close relative of your child been diagnosed with a congenital immunodeficiency?	Yes	No		
Has a close relative of your child ever felt ill after receiving a vaccination?	Yes	No		
To date, has your child received a blood transfusion or been injected with gamma globulin?	Yes	No		
Do you have any questions about today's vaccination?	Yes	No		

Field for doctor to enter

Based on the above questionnaire and the results of the medical examination, I have decided that the child **(can / should not)** receive today's vaccination.

I have explained to the parent/guardian the information concerning the benefits and side effects of vaccination (particularly intussusception) and the Relief System for Injury to Health with Vaccination.

Signature or name and seal of doctor:

Field for parent/guardian to enter

My child has been examined by and I have been provided with information by the doctor. I understand the benefits, objectives, possibility of serious side effects (particularly intussusception), and information concerning the Relief System for Injury to Health with Vaccination, and accordingly I **(do / do not)*** give consent for my child to be vaccinated. * Please circle your choice.

I understand that the purpose of the questionnaire is to ensure the safety of vaccinations and I agree that this questionnaire can be submitted to the municipal office.

Signature of parent/guardian:

Vaccine used	**Dosage**		**Place of vaccination/doctor's name/date of vaccination**
Vaccine name:	**Oral vaccination**		Place of vaccination:
Lot no.:	RotaTeq®	Rotarix®	Doctor's name:
Warning: Confirm that expiration date of vaccine is valid	2 ml	1.5 ml	Date of vaccination: / / (YYYY/MM/DD)

[Reference 4] Post-vaccination health survey

This table summarizes the incidence of fever and local reactions based on the Ministry of Health, Labour and Welfare 2023 post-vaccination health survey summary report. It also summarizes the values of the relatively possible typical post-vaccination symptoms of rotavirus, BCG, and HPV. This table includes both single and simultaneous vaccinations. Since there are many types of vaccines given between the ages of 0 and 1, they are often given simultaneously. Please refer to the report for the health condition after simultaneous vaccination.

2023 Survey on Health Status after Vaccination

*Includes the all incidence rates during the survey period (28 days).

Vaccine type*	Number of people surveyed	All cases of fever (%)	37.5°C to 38.4°C (%)	38.5°C or higher (%)	Local reaction (%)
DPT-IPV phase 1 1st dose (primary)	351	11.6	8.2	3.4	8.5
DPT-IPV phase 1 2nd dose (primary)	318	22.0	14.8	7.2	11.9
DPT-IPV phase 1 3rd dose (primary)	364	11.3	8.5	2.7	12.9
DPT-IPV phase 1 booster	327	13.5	7.6	5.8	11.9
DT phase 2	586	4.8	1.4	3.4	21.0
MR phase 1	603	13.6	6.5	7.1	4.1
MR phase 2	398	7.5	3.3	4.3	3.8
Japanese encephalitis phase 1 1st dose (primary)	418	14.8	6.2	8.6	2.9
Japanese encephalitis phase 1 2nd dose (primary)	273	5.9	2.2	3.7	1.8
Japanese encephalitis phase 1 booster	421	7.4	3.8	3.6	3.6
Japanese encephalitis phase 2	424	5.4	2.4	3.1	8.7
Hib phase 1 1st dose	437	12.8	11.4	1.4	6.4
Hib phase 1 2nd dose	270	22.6	14.1	8.5	10.7
Hib phase 1 3rd dose	313	12.8	9.6	3.2	7.3
Hib booster	277	19.5	8.3	11.2	11.9
Pediatric pneumococcus phase 1 1st dose	409	12.0	9.8	2.2	9.8
Pediatric pneumococcus phase 1 2nd dose	438	21.7	14.8	6.8	17.6
Pediatric pneumococcus phase 1 3rd dose	316	10.4	8.2	2.2	16.8
Pediatric pneumococcus booster	328	18.0	10.7	7.3	22.9
Varicella 1st dose	696	15.2	9.2	6.0	5.0
Varicella 2nd dose	479	10.4	4.6	5.8	3.5
Hepatitis B 1st dose (primary)	428	13.1	10.3	2.8	4.0
Hepatitis B 2nd dose (primary)	347	18.2	13.8	4.3	10.7
Hepatitis B 3rd dose (primary)	390	4.6	3.3	1.3	6.7

Vaccine type*	Number of people surveyed	All cases of fever (%)	37.5°C to 38.4°C (%)	38.5°C or higher (%)	Diarrhea (%)
Rotavirus phase 1 1st dose	650	11.7	9.2	2.5	4.6
Rotavirus phase 1 2nd dose	495	17.4	11.1	6.3	3.8
Rotavirus phase 1 3rd dose	116	10.3	7.8	2.6	4.3

For BCG, the incidence of "lymphadenopathy" and "local skin weeping" as relatively possible typical symptoms, as well as that of "total incidence of all symptoms", are shown. Only the BCG survey period is 4 months.

Vaccine type	Number of people surveyed	Lymphadenopathy (%)	Local skin weeping (%)	Total incidence of all symptoms (%)
BCG	958	0.0	0.1	0.1

For vaccines in the table below, the incidence of "lymphadenopathy" and "local skin weeping" as relatively possible typical symptoms, as well as that of "total incidence of all symptoms", are shown.

Vaccine type*	Number of people surveyed	Local reaction (%)	General malaise (%)	Headache (%)	Total incidence of all symptoms (%)
HPV 1st dose	320	11.6	7.2	7.5	18.4
HPV 2nd dose	370	12.7	3.8	2.4	15.9
HPV 3rd dose	219	9.1	3.7	7.3	14.2

References (for details, see: https://www.yoboseshu-rc.com/publics/index/7)

1 Vaccination Guidelines

March 2025 revised edition (A5 size)
A guidebook on medical and regulatory information about vaccination for medical staff in practice to conduct safe and appropriate vaccination.

2 Vaccination Guidelines for Category B Diseases

2024 revised edition (A5 size)
An overview of medical and regulatory information on routine vaccinations for influenza, pneumococcal infection in the elderly, and COVID-19 infection.

3 Vaccination handbook

2024 edition (A4 size)
A handbook for doctors who give vaccination and municipal staff in charge of vaccination.

4. Editions in foreign languages “Vaccination and children’s health”

March 2024 revised edition
“Vaccination and children’s health,” a brochure containing correct knowledge and information concerning vaccination for parents/guardians and the vaccination screening questionnaire, is translated in the following languages and available from the following site. Please download them as required.

https://www.yoboseshu-rc.com/publics/index/8/

The entire brochure is available in the following 10 languages:
English, Chinese, Korean, Vietnamese, Spanish, Portuguese, Thai, Indonesian, Tagalog, and Nepalese
The vaccination screening questionnaire alone is available in the following seven languages:
Arabic, Italian, German, French, Mongolian, Russian, and Ukrainian.

5 Learn about vaccinations with your children

August 2023 edition (A5 size)
With a comic aimed at children and guidance aimed at parents/guardians, this one book will allow you to better understand vaccinations.

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