

The target patients (Born on April 2nd 1995 till April 1st 2007) must be younger than 20 years of age (Before their Birthday).

Date as of August, 2018

Japanese Encephalitis Vaccine Explanation/ Consent form

(Target group from age 13 to under the age of 20 and without the presence of the guardian)

Explanation regarding the Japanese Encephalitis Preventive Vaccination

~ Please read it carefully. It contains information indispensable about the vaccination ~

For guardians: Please read the content carefully.

If the vaccinee is not accompanied by the guardian, the back page and the vaccination questionnaire form must be signed by the guardian before handing in to medical institution.

Regarding the Japanese Encephalitis vaccination for people over 13 years of age, the guardian who wishes your child to undergo the vaccination, after having read, understood and consent the matters mentioned here, **signing the consent form on the reverse side of this leaflet and the medical history questionnaire form, the child may undergo the vaccination even without the presence of the guardian. (On the vaccination date, remember to take this leaflet and the questionnaire form).**

By the time you sign the consent form as well as the questionnaire, if you have any doubts, please contact your physician or the Health Promotion Division of your district and only after getting enough information decide about the vaccination.

1. Japanese Encephalitis Symptoms

Japanese Encephalitis (JE) is an illness that through infection of JE viruses affects the central nervous system (brain and spinal cord). The infection is not spread directly (person to person). Actually, it occurs when the principal vector, *Culex Tritaeniorhynchus* (specie of mosquito that develops mainly in rice fields), bites animals such as pigs in which internal body the virus had multiplied (infected) and then, bites a human afterwards.

In most cases there are no symptoms (unapparent infection) (it was reported in the past that among 100 to 1000 infected people, one became ill). However, in case the symptoms appear, after 6 to 16 days of incubation period, there is high fever for few days, headache, vomiting, among others. Moreover, continuous and sudden symptoms such as light hypersensitivity, consciousness disorder (pass out), seizures, etc., or disorders related to nervous system (brain disorder) may occur. The majority of people don't have any symptoms even if they are infected, but if encephalitis occurs the death rate is 20 to 40%. The circumstances for the infection are different depending on the region.

For detailed information, please check the Information and Research National Center for Contagious Diseases Homepage.

2. The Effectiveness and Side Effects of Japanese Encephalitis Vaccination

The JE dry cell culture vaccine which is used these days, is manufactured by taking the JE viruses, multiplying them in Vero cells (kidney cells extracted from African green monkey), collecting the resultant cells and inactivating them with formalin (elimination of the toxicity). Children who receive the vaccination will get a good immunization.

Depending on the vaccination, light side effects may appear. However, although rare, heavy side effects may also occur. The reactions commonly seen after vaccinations are described according to the following topic (Main JE vaccination side effects).

Those who had used the old JE Stage 1 vaccination produced from hamster brain in the past can take the remaining shots of 1st stage vaccination and 2nd stage using the new JE dry cell culture vaccine. Related to that fact, in 2010, in order to evaluate the neutralization degree of antibodies before and after the vaccination, a scientific research by the Ministry of Labor and Welfare was conducted in approximately 288 people (81 people who got initial 2 shots of the old Hamster brain vaccine on Stage 1 and a stage 1 booster shot of the new one; 46 people who got 3 shots of the new vaccine on stage 1 and stage 2, 161 people who got 3 shots of the old vaccine on stage 1 and the new vaccine on stage 2). As a result, it was verified a significant rise of the level of antibodies on people who took the new vaccine even though having taken the old vaccine before. In addition, it was not reported that this vaccination method had caused any heavy injuries to health.

○ Main Japanese Encephalitis Vaccination Side Effects

There are two types of JE dry cell culture vaccines (A and B) being used that are manufactured and sold within Japan. The differences between the two cannot be compared as the clinical studies of them are conducted separately but according to the attached content regarding the vaccine, young children between 6 months to under the age of 90 months are known to show the following side effects. For A, 49 children (39.8%) had reaction that mainly was: fever (18.7%), coughing (11.4%), running nose (9.8%), and redness at the injection site (8.9%). Most of these side effects are observed until 3 days after the vaccination. Also, for B, 84 cases out of 163 (51.5%) showed side effects, the most primary one being breaking out in a fever (21.5%), Red spots near the injection (16.6%), Coughing (8%), Swelling of the Injected area (6.7%), Runny nose (6.7%), and Rashes (5.5%), most of these side effects are observed until 3 days after the vaccination.

However, occurrences of severe side effects such as Shock, Anaphylaxis, Acute Disseminated Encephalomyelitis (ADEM), brain fever, seizures, severe thrombocytopenic purpura, are also observed.

Since 2013, according to the figures from the report of JE Dry Cell Culture Vaccinations side effects from Ministry of Labor and Welfare in 121 cases (The figures were based of those from the "Outline of Routine Inoculations". The report, regardless of whether a causal relationship exists or not between vaccinations and symptoms, informs us of changes to one's health caused by vaccinations. This includes not just the reactions caused depending on different vaccines but outbreak incident to which relationship to vaccines is unthinkable.), primarily 18 cases were convulsions, 7 cases of ADEM etc. and as serious side effects there were 3 cases of Encephalitis and Encephalopathy.

For detailed information, please check the Information and Research National Center for Contagious Diseases Homepage.

※Still, there might be cases of ADEM after administration of other types of vaccines besides of the JE vaccine. A case of ADEM occurred through vaccination of another dry cell culture vaccine was reported in foreign country.

Continues

3. The Relief System Supporting for Health Injury due to Vaccination

- In case health injuries occur due to side effect of routine vaccination, impairing the person to perform daily activities, compensation according to the Preventive Law can be obtained.
 - However, a group of governmental specialists in fields such as of vaccination, contagious diseases, treatments, laws, etc will evaluate the relation between the cause and effect of the vaccine and determine if the health injury was in fact caused by the vaccination or by other reasons (such as contagious disease contracted before or after vaccination or else for another reason). The compensation is paid to the patient only after being proofed that the health injury was caused by the vaccination.
 - The compensation consists of payment of medical expenses, medical benefits, disabled child's annuity, disability annuity, lump-sum death benefits, funeral expenses and additional care, all of which are designated by law according to the severity of the health injury. Except lump-sum death benefits and funeral expenses, the compensation will be paid continually until the completion of treatment or improvement of the health injury.
 - The Japanese Encephalitis vaccination carried out this time is directed for people who were born between April 2nd of 1995 and April 1st of 2007, which it means that, the vaccination is carried out for individuals under the age of 20. However, in case the individual wishes to have the vaccination after the designated period, it will not be based on the Vaccination Law (voluntary vaccination). If health injuries occur due to the vaccination, compensation will be granted according to Pharmaceuticals and Medical Devices Agency Law, but the amount received is approximately half less if compared to the amount received for vaccinations based on the Vaccination Law (regarding the medical expenses, medical benefits and funeral expenses the compensation amount is about the same.)
- ※ For compensation advice, please contact the Health Promotion Division.

4. Cautions when applying the vaccination

By general rule, the vaccination should be carried out whenever the person is in good health. On the contrary, if he/she is not well, only after consulting the physician giving you the vaccine, you may decide whether your child should or shouldn't undergo the vaccination.

Persons who fall under the following situation cannot undergo the vaccination.

- ① person with an obvious fever (usually over 37.5 °C)
- ② person who has any acute disease
- ③ person who had experienced anaphylaxis in response to an ingredient contained in the Japanese Encephalitis vaccinations.
- ④ person who has obvious immunodeficiency or who is currently in treatment for immunity control.
- ⑤ Others, the physician judged the person's condition is not appropriate for the vaccination.

【Cautions for women】

If the person is pregnant or possibly pregnant, a general vaccination can not be carried out. However, if it is judged that the benefits of the vaccination overcome the risk it can cause, then only in this case the vaccination is possible. Therefore, consult your physician and only after that, decide whether or not to get the vaccination.

For guardians: Please read the following carefully.

Only after reading, getting enough understanding, and accepting the explanation mentioned, decide to give your child the vaccination. Once you have decided, please sign on "Guardian's Signature". **(Without the guardian's signature, the vaccination will not be carried out if the child is not accompanied by the guardian.)**

The signature is unnecessary if you are not willing to give your child the vaccination.

Consent Form

Having read and understood the explanation about the Japanese Encephalitis vaccine; its aims, effects, the risk of serious side effects, as well as the vaccine injury compensation program, I agree to my child to receive the vaccination.

I do also understand that this explanation form has the purpose to deepen the guardians understanding regards the immunization. Therefore, I do consent the submission of this form to Hamamatsu city.

保護者自署 Guardian's Signature : _____

住所 Address : Hamamatsu-shi _____

緊急の連絡先 (電話番号等) Emergency Contact (Phone #) : _____

※ This Japanese Encephalitis vaccination form will be necessary in case the guardian doesn't go with the child. In case the child goes alone, make sure this form as well as the questionnaire form to be handed at the medical institution.

If this form and the questionnaire form are not signed by the guardian and if he/she doesn't accompany the child, then the vaccination will not be carried out.

