

Press Release

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Q and A

Resuming vaccination with the pediatric pneumococcal conjugate vaccine and the Hib vaccine

March 29, 2011

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Q1. Why was vaccination of the pediatric pneumococcal conjugate vaccine and the Hib vaccine suspended?

The four fatal cases have been reported after simultaneous vaccination of the pediatric pneumococcal conjugate vaccine and the Haemophilus influenza type b (Hib) vaccine between March 2 and March 4, 2011. According to the doctors who reported cases, causal relationships to deaths cannot be confirmed or are not clear. Since then, additional three fatal cases have been reported. (Those seven cases include the cases which occurred in past times)

Until collecting further information and implementing the assessment of causal relationship by experts, the MHLW suspended the vaccination on a temporary basis just to be safe between March 4 and March 31.

* The MHLW decided to resume vaccinations from April 1, 2011. (Refer to Q2, Q3)

Q2. What evidence do vaccinations of the pediatric pneumococcal conjugate vaccine and the Hib vaccine resume based on?

The Joint meeting of experts on March 24 evaluated those cases based on varied information obtained from

either internal or external sources and concluded that there is no safety concern because of the reason which is described in Q3.

Q3. Are the pediatric pneumococcal conjugate vaccine and the Hib vaccine safe?

These vaccines are commonly used in overseas. And it is estimated that approximately one million people to one and a half million children were vaccinated in Japan. The fatal cases after vaccinations have been reported within the country. The Joint meeting of experts reviewed those fatalities and diverse information in Japan and overseas, and concluded that there was no safety concern because of the following reasons.

- The joint meeting considered that there are no direct and clear causal relationships between the vaccination of pneumococcal conjugate vaccine and Haemophilus influenza type b (Hib) vaccine and a series of deaths as of this moment.
- Considering the frequencies of reported fatal cases after simultaneous vaccination of pneumococcal conjugate vaccine and Haemophilus influenza type b (Hib) vaccine, there is not much difference between that of in Japan and foreign countries, and thus it is unlikely that the safety of the vaccinations of these vaccines in Japan are particularly questioned.
- According to the researches both in Japan and overseas, when simultaneous multiple vaccinations including these vaccines, there have been reported that minor adverse reactions such as fever or injection site swelling increased. However; increase of severe adverse reactions is not shown.

After vaccination, in general, minor adverse reactions such as fever or injection site swelling may occur at a certain rate and serious adverse reactions may be found only rarely. Please note the following cautions described in Q 4.

Q4. How should we exercise caution, when simultaneous vaccinations of the pneumococcal conjugate vaccine and the Hib vaccine?

Generally, vaccination should be made when your child has no fever and acute disease. In addition, a doctor is required to obtain your child's medical history / examination and measuring temperature before vaccination. If you have your personal physician familiar with your child's condition, it is appropriate to receive vaccination by the doctor or to consult her/him.

Please refer to Q5 for safety of simultaneous vaccination with multiple vaccines, Q6 for precautions for the patients who have underlying diseases, Q8 for cautions after vaccination.

Q5. Is simultaneous vaccination of the pneumococcal conjugate vaccine and the Hib vaccine safe? Also is simultaneous vaccination of those vaccines and the DPT vaccine (diphtheria pertussis tetanus vaccine) safe?

According to the researches study in Japan and abroad, in the case of simultaneous vaccination with multiple vaccines including pneumococcal conjugate vaccine and Hib vaccine, there have been reported that minor adverse reactions such as fever or injection site swelling increased, but some researches showed that significant differences were not found in minor adverse reactions between simultaneous vaccination with

multiple vaccines and single vaccination.. Further, increase of severe adverse reactions related to simultaneous vaccination is not shown. In Europe and U.S., it is concluded that there is no safety concern of simultaneous vaccination, and simultaneous vaccinations are commonly used there.

For above reasons, MHLW concluded that simultaneous vaccination of those two vaccines has no particular safety concern based on currently available information.

Q6. If my child has an underlying disease (a chronic disease), should my child avoid the vaccination? Can my child receive the vaccination?

Generally, children with underlying diseases are at increased risk of worsen infection compared with healthy children. Thus, for these children, serious infection including meningitis and sepsis should be prevented in early phase; on the other hand adverse reactions to vaccination should be paid more attention. For example, a child with severe underlying disease including severe cardiac disease should receive vaccination by a family doctor who is familiar with the child's medical condition, or an experienced doctor for vaccination kept in touch with the family doctor should administer of the vaccine with caution following checking up the child's medical condition thoroughly and deciding the appropriate timing for vaccination.

You should consult your family doctor about simultaneous vaccination with multiple vaccines, so that the doctor can decide to do it cautiously considering the option of single vaccination. Simultaneous vaccination with multiple vaccines may have advantages including getting early immunization and less frequently visiting the doctor, and doesn't increase serious adverse reactions. On the other hand in case of a serious adverse reaction, single vaccination allows to identify association with the vaccination easier than simultaneous vaccination.

Q7. If it took longer interval between vaccinations than recommended because we passed the due date during the period of suspended vaccination, can my child receive the vaccination?

Even if your child didn't receive the vaccination on schedule or it took longer interval between vaccinations than recommended due to suspended vaccination, the immunogenicity after vaccination wouldn't be affected.

Your child should receive the vaccination immediately to obtain immunogenicity, even if the interval for the vaccination became a little longer.

* Withdrawal of a certain lots of the Hib vaccine due to foreign particles may result in the shortage of the vaccine transiently in some area. If you want your child to receive the vaccine, you should confirm it with a medical institution.

Q8. After vaccination, how long do we have to be careful? And, what do we have to be cautious about?

After vaccination, your child may have mild fever, injection site swelling or rare but serious adverse reaction. Otherwise, your child may develop a disease coincidentally after vaccination. Usually adverse reactions including fever or swelling related to inactivated vaccines such as the Hib vaccine or the pneumococcal vaccine occur on the day of vaccination or within a few days after vaccination, and self-limiting. Extremely

rare adverse reaction including thrombocytopenic purpura may occur within 3 weeks after vaccination. If hyperthermia, fatigue, convulsion or seizure, or unconsciousness occur, your child should receive immediate medical attention.

Q9. What should we do in case of getting sick after vaccination? And, what should we do when the patient may experience an adverse effect of the vaccine?

After vaccination, your child may experience adverse reactions including symptoms described in Q8. If hyperthermia, fatigue, convulsion or seizure, or unconsciousness occurs, your child should receive immediate medical attention.

Should your child have a serious adverse reaction or an irreversible disability related to the Hib vaccine or the pediatric pneumococcal conjugate vaccine, you may consult with your local government. A local government that implements the project for urgent promotion of vaccination takes part in the insurance for adverse health effects. Or your child may be eligible for the Relief System for Sufferers from Adverse Drug Reactions.