Japan Council for Quality Health Care

Project to Collect Medical Near-Miss/ Adverse Event Information

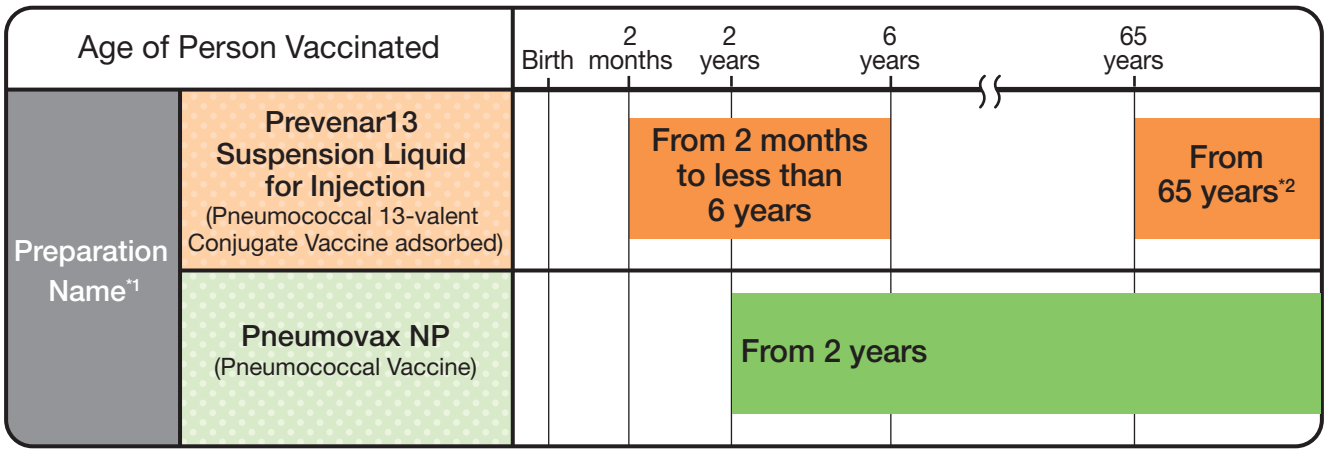
Medical Safety Information

No.97, December 2014

Wrong Choice of Pneumococcal Vaccine Preparation

Two cases have been reported involving a person vaccinated with the wrong pneumococcal vaccine preparation because the medical professionals involved were unaware of the age recommendations for the preparation concerned (information collection period: from January 1, 2011 to October 31, 2014). The information is compiled based on “Individual Theme Analysis” (p.106) in the 23rd Quarterly Report.

There are specific age recommendations for pneumococcal vaccine preparations, so the choice of preparation is governed by the age of the person being vaccinated.



*1 From PMDA, Information on Package Inserts for Prescription Drugs (as of November 17, 2014)
*2 On June 20, 2014, the recommendation was extended to include those aged 65 years and over as well.

- The “Persons Who Should Not be Vaccinated” section of the Pneumovax NP package insert states, “This product should not be administered to infants less than 2 years of age, because they do not develop an effective immune response to the capsular antigens that it contains and its safety among this age group has not been established.”
- Both reported cases involved vaccination of infants less than 2 years of age with Pneumovax NP.

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Case 1

The mother of a pediatric patient aged 2 months booked an appointment, requesting simultaneous administration of the Haemophilus influenzae type b (Hib) vaccine and the pneumococcal vaccine. The outpatient nurse who took the booking did not know that the type of pneumococcal vaccine that should be used differed according to the age of the patient, so s/he wrote “Hib vaccine, pneumococcal vaccine” on the appointment slip, which also bore the patient’s age, and sent a request to the pharmaceutical department for the vaccines. The pharmacist handling the request was also unaware of the age recommendations for each pneumococcal vaccine preparation and ordered “pneumococcal vaccine” from the supplier. On the day of the vaccination, the outpatient nurse obtained the Hib vaccine and pneumococcal vaccine from the pharmaceutical department and vaccinated the patient after the infant’s consultation with the physician. About a month later, another medical institution contacted the medical institution in question to inform them that a lot number for Pneumovax NP had been affixed to the pediatric patient’s maternal and child health handbook. When the record was checked, staff discovered that the infant had been vaccinated with Pneumovax NP instead of Prevenar.

Case 2

When administering pneumococcal vaccine as part of a local government immunization program, the physician requested that pneumococcal vaccine be dispensed, without being aware that Prevenar should be used for infants less than 2 years of age. The pharmacist dispensed Pneumovax NP, without checking the ages of the children to be vaccinated. Having vaccinated a total of 4 infants (aged 6 months, 7 months, 10 months, and 1 year and 5 months) with Pneumovax NP, the physician submitted an invoice for the cost of the vaccine preparation to the local government. Subsequently, the local government contacted the physician to inform him/her that infants less than 2 years of age had been vaccinated with Pneumovax NP.

Preventive measures taken at the medical institutions in which the events occurred.

- **The medical institution will post a list of the types of immunization they carried out, along with the brand name of each preparation and the ages for which it is recommended.**
- **The physician will order separate prescriptions of pneumococcal vaccines for each individual to be vaccinated and the pharmacist will dispense them only after auditing the prescription.**

* As part of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this medical safety information was prepared based on the cases collected in the Project as well as on opinions of the “Comprehensive Evaluation Panel” to prevent the occurrence and recurrence of medical adverse events. See quarterly reports and annual reports posted on the Japan Council for Quality Health Care website for details of the Project.
http://www.med-safe.jp/

* Accuracy of information was ensured at the time of preparation but cannot be guaranteed in the future.

* This information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.

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