

**NEW PNEUMOCOCCAL VACCINE**

No. 11, 2001

**New pneumococcal vaccine for children under 2 years of age**

At the end of February 2001 a new pneumococcal vaccine was registered in Denmark for the prevention of invasive pneumococcal diseases such as meningitis and septicaemia in children under 2 years of age. This is a new type of vaccine, which unlike the existing 23-valent pneumococcal polysaccharide vaccine can be used for children down to the age of 2 months. The new pneumococcal vaccine is 7-valent and produced by coupling capsular polysaccharide from seven types of pneumococci to the protein CRM<sub>197</sub>, which makes the vaccine immunogenic even in infants. The types of pneumococci included in the vaccine are those that most often produce serious infections in children in the USA and many other countries.

**Efficacy of the new vaccine**

Since the beginning of the year 2000 the vaccine has been licensed in the USA and recommended for all children under 2 years and those aged 2-5 years at special risk of serious pneumococcal disease. Before approval the vaccine was tested in the USA on about 38,000 healthy children who were vaccinated at the age of 2, 4 and 6 months and later at 12-15 months. The trial showed that the vaccine prevented about 97% of cases of meningitis and septicaemia due to the pneumococcal types included in the vaccine, and 89% of cases due to all types of pneumococci in children. The trial also showed that the vaccine prevents almost 10% of all cases of otitis media, 34% of pneumococcal otitis media, and 20% of ventilatory tube placements. The vaccine was also shown to prevent a proportion of cases of pneumococcal pneumonia, i.e. 11% of all clinical cases of pneumonia and 34% of all pneumonia cases diagnosed by chest x-ray. Some preliminary observations suggest that extensive use of the 7-valent pneumococcal vaccine could change the distribution of the types of pneumococci that are circulating in the community, so that other types may become more frequent and thus reduce the efficacy of the vaccine. However, this has only been found for cases of otitis media and not for invasive disease. Studies

**Table 1. Dosage of 7-valent conjugated pneumococcal vaccine for use in at-risk children aged 2-23 months**

Age at 1st vacc.	Primary vaccination series	Booster-dose
2-6 months	3 doses at 6-8 weeks interval	1 dose at 12-15 months
7-11 months	2 doses at 6-8 weeks interval	1 dose at 12-15 months
12-23 months	2 doses at 6-8 weeks interval	-

to investigate this phenomenon are now in progress in various countries including the USA.

**Side effects**

The new pneumococcal vaccine is safe and only gives rise to various known side effects that are also seen after Hib vaccination, if somewhat more frequently. These are redness, swelling and soreness at the injection site in about 10%, as well as fever following vaccination in up to 25%, usually with a temperature below 39°C. The stated frequency of febrile reactions is based on the simultaneous administration of other childhood vaccinations, e.g. DTaP-IPV vaccine.

**Pneumococcal infections in children in Denmark**

A survey of the number of cases of invasive pneumococcal disease in children under the age of 6 years in Denmark during the period 1981-99 has shown that there are about 80 cases per year, approximately 18 of these being pneumococcal meningitis. It is especially children under 2 years that get these infections and the risk then declines with age. The survey also showed that the seven types of pneumococci in the vaccine cover about 60% of invasive pneumococcal infections in children under 6 years in Denmark. This means that if the new 7-valent pneumococcal vaccine were to be introduced into the childhood vaccination programme, it would probably prevent about 50 cases per year of invasive pneumococcal disease in children under 6 years of age.

**Risk groups**

The following groups of children are at special risk of serious pneumococcal infection:

- Children with asplenia or impaired splenic function
- HIV-positive children
- Children with chronic heart, lung or kidney disease
- Children with diabetes mellitus

- Children with immune defect or under immunosuppressive therapy

- Children with CSF leakage.

However, at present there are no data to show that the vaccine prevents serious pneumococcal infection in these risk groups.

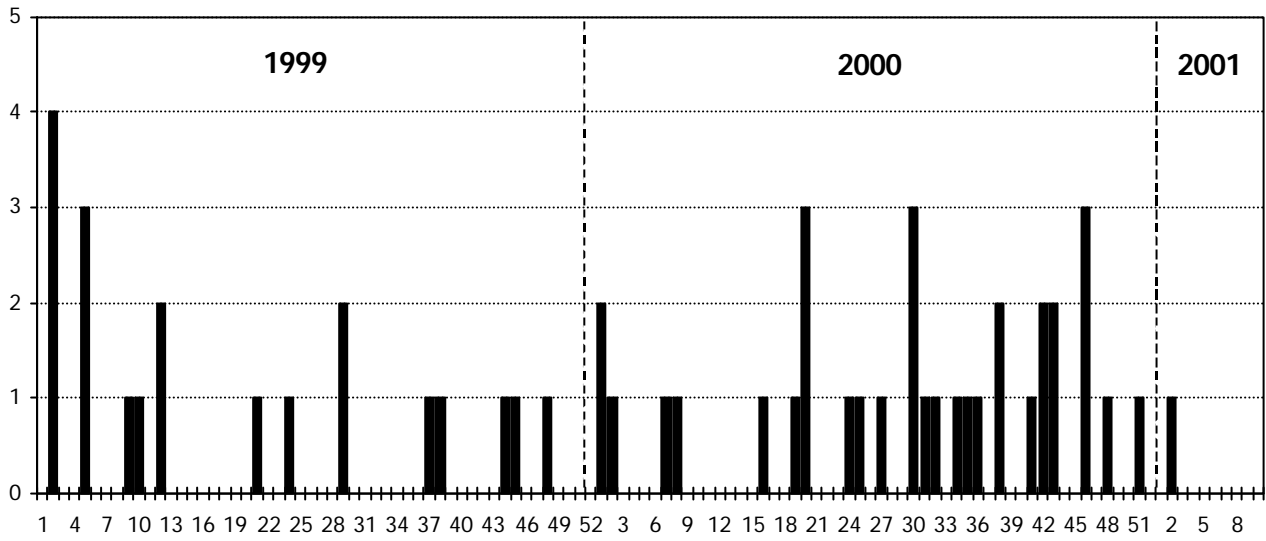
**Suggested use**

The Vaccination Committee of the National Board of Health has decided the vaccine should not at present be included in the Danish childhood vaccination programme as a free offer. The new pneumococcal vaccine is very expensive (about 500 DKK per dose excluding VAT) and new 9- and 11-valent pneumococcal vaccines with a broader range of protection are expected within the next few years. In addition, there is the uncertainty about the changes in circulating types of pneumococci mentioned above. It is therefore recommended that the vaccine should primarily be used in children under 2 years who are at special risk.

**Administration**

In children under 2 years the pneumococcal vaccine should be given at the age of e.g. 3, 5, 7 and 15 months. There must be an interval of at least 6-8 weeks between successive doses, table 1. The vaccine can be given simultaneously with the other childhood vaccines, but by a separate injection at a separate site. The vaccine must be given intramuscularly. Children in the listed risk groups who have been vaccinated with the 7-valent pneumococcal vaccine should be vaccinated with the 23-valent polysaccharide vaccine after their 2nd birthday, but at least 8 weeks after the last dose of conjugated vaccine was given. This is to obtain a stronger and broader antibody response. At-risk children over the age of 2 years should be vaccinated as hitherto with the 23-valent vaccine, EPI-NEWS 44/99. (H.B. Konradsen, ALMOS, M. Stellfeld, Dept. of Medicine, T. Rønne, Dept. of Epidemiology)

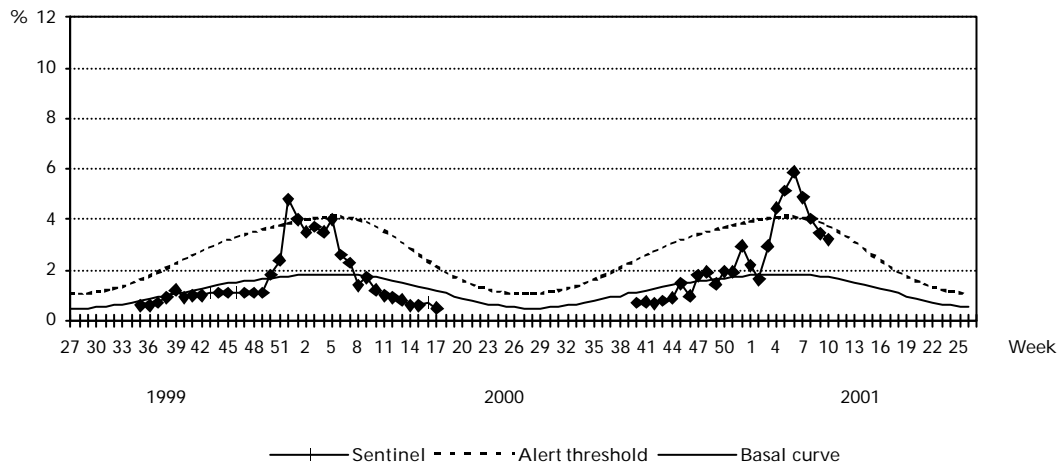
**No. of notified cases of mumps per week, 1999 - 13 March 2001**



(Dept. of Epidemiology)

**Sentinel surveillance of influenza activity**

Weekly percentage of consultations, 1999/2000/2001



- Sentinel:** Influenza consultations as % of total consultations
- Basal curve:** Expected frequency of influenza consultations under non-epidemic conditions
- Alert threshold:** Possible incipient epidemic

(Dept. of Epidemiology)