EPI-NEWS

NATIONAL SURVEILLANCE OF COMMUNICABLE DISEASES

Editor: Peter Henrik Andersen
Dept. of Epidemiology
Statens Serum Institut • 5 Artillerivej • DK 2300 Copenhagen S

Tel.: +45 3268 3268 • Fax: +45 3268 3874
www.ssi.dk • epinews@ssi.dk • ISSN: 1396-4798

PNEUMOCOCCAL VACCINE IN CHILDHOOD VACCINATION PROGRAMME No. 37a, 2007

On 1 October 2007 vaccination using heptavalent conjugated pneumococcal vaccine (PCV7) will be introduced to the Danish childhood vaccination programme.

Vaccination programme
PCV7 will be given as three 0.5 ml doses when the child is 3, 5 and 12 months of age, i.e. concurrently with the DTaPIPV/Hib vaccine. The two vaccines should be administered as intramuscular injections at separate injection sites. PCV7 should be administered in the side of the outer anterior part of the thigh (lateral great muscle) in children below the age of 1 year and in the upper arm (deltoid muscle) in older children. It is recommended that PCV7 be administered to the left side.

Introduction programme
During the introduction period, children born after 30 April 2006 who are 4-17 months by October 2007 will also be offered the vaccination (see table on reverse of EPI-NEWS 37b/07). Such children will receive a letter informing them of the introduction programme.
Children who at the first vaccination are 4-11 months old will be offered three vaccinations. The minimum interval between the two first vaccinations is one month, and the second and third vaccination should be separated by a minimum interval of two months. The third vaccination should be administered when the child is at least 12 months old.
Children aged 12-17 months at first vaccination will be offered two vaccinations with a minimum interval of two months.

Service code
Specific administrative service codes have been created for the first (8344), second (8345) and third (8346) PCV7 dose. Where a child participates in the introduction programme and only receives 2 doses, the first (8344) and second (8345) service codes should be used.
It is essential that the correct codes are used for all vaccinations. The service codes constitute the foundation of the Danish childhood vaccination registry and will be used for the ongoing monitoring of vaccination coverage.

Pneumococcal disease
Pneumococcal disease is caused by the pneumococcal bacterium (Streptococcus pneumoniae), which is a Gram-positive bacterium with a polysaccharide capsule. There are 91 known types of pneumococci. Pneumococci are an important causal factor of sinusitis, otitis media, pneumonia and invasive diseases, including sepsis and meningitis. The highest occurrence of invasive pneumococcal disease is found in children under the age of two years and in elderly persons above the age of 64 years. The risk of invasive pneumococcal disease diminishes considerably towards the age of two years and children above four years of age only have a very limited risk of invasive pneumococcal disease.
Pneumococci are the primary cause of bacterial meningitis in Denmark. In children below the age of five years, pneumococcal meningitis constitutes nearly 1/3 of all invasive pneumococcal disease cases: 13% suffer permanent events including hearing loss and brain damage, and 7% die.

Conjugated pneumococcal vaccine
In children under the age of 2 years, the immune system is not yet sufficiently matured to react effectively to pure polysaccharide vaccines. By using a vaccine in which the pneumococcal capsule polysaccharides 4, 6B, 9V, 14, 18C, 19F and 23F are coupled (conjugated) to a carrier protein, the needed protection against invasive pneumococcal disease caused by these types of pneumococci is achieved. The same conjugation principle is used in the current Hib vaccine.
The seven pneumococci types included in PCV7 cause 64% of all cases of invasive pneumococcal disease in children below the age of five years in Denmark. In the age group from six months to two years, PCV7 protects against 75% of invasive pneumococcal disease. Thus, invasive pneumococcal disease may still occur even among vaccinated children due to the types of pneumococci that are not part of PCV7.

Adverse events
PCV7 has been registered in Denmark for more than two years and mandatory notification only covers unexpected or serious adverse events.
Given concurrently with the DTaP-IPV/Hib vaccine, adverse events are expected in the form of fever $\geq$ 38°C in up to half of the vacinees and > 39.5°C in up to 3 % of the vacinees. Consequently, fever cramps may occur. After vaccination drowsiness, irritability, unsettled sleep, vomiting, diarrhoea and reduced appetite frequently occur. Local reactions presenting as tenderness and swelling is expected in 35-40% of the vacinees.

Expected effect of the introduction of pneumococcal vaccination
Once all children in the age group below five years have received PCV7 vaccination, the programme is expected to reduce the annual number of invasive pneumococcal disease cases by 50 and prevent one annual death among children below the age of five years.
The PCV7 vaccination is also expected to reduce the occurrence of upper and lower respiratory infections caused by pneumococci, EPI-NEWS 37b/07.
Furthermore, vaccination of children is expected to reduce the spread of pneumococci in the entire population. Consequently, it is estimated that the vaccination may prevent about 150 additional cases of invasive pneumococcal disease and 30 deaths annually, primarily among the elderly. The scope of such indirect effect depends on vaccination coverage and on the degree to which the types of pneumococci covered by the vaccination will be replaced by others not found in the current vaccine.

Mandatory laboratory notification
To improve the monitoring of the pneumococcal vaccination's effect under the childhood vaccination programme, notification of all invasive pneumococcal diseases is made mandatory for laboratories as from 1 October 2007. Notification should be made to Statens Serum Institut.

Commentary
PCV7 has formed part of the childhood vaccination programme of the U.S. since 2000. In the American context, a 4-dose regimen has led to considerable reduction of invasive pneumococcal disease cases in vaccinated children and some reduction among elderly adults. This indirect effect among the elderly is attributed to herd immunity protection. Several other European countries have introduced PCV7 to childhood vaccination programmes as 3-dose regimens, including Norway in 2006 and Great Britain and Belgium in 2007.
(P. Valentiner-Branth, P.H. Andersen, A.H. Christiansen, L. Vestergaard, S. Glismann, Dept. of Epidemiology, J.J. Christensen, Z.B. Harboe, H.B. Konradsen, DBMP)

12 September 2007

Individually notifiable diseases

Number of notifications received in the Department of Epidemiology, SSI (2007 figures are preliminary)

Table 1	Week 36 2007	Cum. 2007 [1]	Cum. 2006 [1]
AIDS	1	37	31
Anthrax	0	0	0
Botulism	0	0	0
Cholera	0	0	0
Creutzfeldt-Jakob	0	6	14
Diphtheria	0	0	0
Food-borne diseases	22	421	375
of these, infected abroad	2	80	89
Gonorrhoea	13	260	313
Haemorrhagic fever	0	0	0
Hepatitis A	1	18	22
of these, infected abroad	0	7	11
Hepatitis B (acute)	1	19	15
Hepatitis B (chronic)	6	195	244
Hepatitis C (acute)	0	4	6
Hepatitis C (chronic)	11	260	367
HIV	5	196	158
Legionella pneumonia	4	73	80
of these, infected abroad	0	16	20
Leprosy	0	0	0
Leptospirosis	0	8	7
Measles	0	2	26
Meningococcal disease	0	50	59
of these, group B	0	27	29
of these, group C	0	17	12
of these, unspec. + other	0	6	18
Mumps	1	4	12
Neuroborreliosis	1	54	41
Ornithosis	0	7	8
Pertussis (children < 2 years)	3	52	35
Plague	0	0	0
Polio	0	0	0
Purulent meningitis			
Haemophilus influenzae	0	2	1
Listeria monocytogenes	0	8	7
Streptococcus pneumoniae	1	81	66
Other aethiology	0	11	6
Unknown aethiology	0	11	16
Under registration	1	10	-
Rabies	0	0	0
Rubella (congenital)	0	0	0
Rubella (during pregnancy)	0	0	0
Shigellosis	31	128	41
of these, infected abroad	2	28	36
Syphilis	5	70	51
Tetanus	1	1	2
Tuberculosis	9	289	259
Typhoid/paratyphoid fever	2	16	20
of these, infected abroad	2	15	20
Typhus exanthematicus	0	2	0
VTEC/HUS	4	113	97
of these, infected abroad	0	31	33

[1] *Cumulative number 2007 and in corresponding period 2006*

Selected laboratory diagnosed infections

Number of specimens, isolates, and/or notifications received in SSI laboratories

Table 2	Week 36 2007	Cum. 2007 [2]	Cum. 2006 [2]
Bordetella pertussis (all ages)	4	138	141
Gonococci	5	258	312
of these, females	1	40	55
of these, males	4	218	257
Listeria monocytogenes	2	37	35
Mycoplasma pneumoniae			
Resp. specimens [3]	6	267	292
Serum specimens [4]	5	315	258
Streptococci [5]			
Group A streptococci	0	84	111
Group B streptococci	3	70	70
Group C streptococci	0	16	16
Group G streptococci	1	88	104
S. pneumoniae	8	730	705
Table 3	**Week 34 2007**	**Cum. 2007 [2]**	**Cum. 2006 [2]**
MRSA	24	396	-
Pathogenic int. bacteria [6]			
Campylobacter	147	2590	1982
S. Enteritidis	8	335	371
S. Typhimurium	19	228	249
Other zoon. salmonella	3	449	405
Yersinia enterocolitica	11	183	118
Verocytotoxin-producing E. coli	6	112	98
Enteropathogenic E. coli	6	122	170
Enterotoxigenic E. coli	13	167	169

[2] *Cumulative number 2007 and in corresponding period 2006*

[3] *Resp. specimens with positive PCR*

[4] *Serum specimens with pos. complement fixation test*

[5] *Isolated in blood or spinal fluid*

[6] *See also www.germ.dk*

Commentary

In week 36, a tetanus notification was received concerning a 68-year-old female who had acquired a necrotic toe wound. She had received her latest tetanus vaccination 30 years ago. (Department of Epidemiology)

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FAQs ON PNEUMOCOCCAL VACCINATION OF CHILDREN

No. 37b, 2007

On 1 October 2007 vaccination using heptavalent conjugated pneumococcal vaccine (PCV7) will be introduced to the Danish childhood vaccination programme, EPI-NEWS 37a/07.

What does the conjugated pneumococcal vaccine (PCV7) contain?
The vaccine contains capsular material from seven types of pneumococci coupled with CRM 197, which is a non-toxic variant of diphtheria toxin. Furthermore, the vaccine contains aluminium phosphate and sodium chloride.

How effective is the vaccine?
A major U.S. trial including 38,000 healthy children who underwent 4-dose vaccination with the heptavalent vaccine yielded 97% protection against invasive pneumococcal disease caused by the types of pneumococci included in the vaccine. Furthermore, studies from the U.S. and Finland have shown that the vaccine prevents 6% of all otitis media cases, 34% of all pneumococcal-associated otitis media cases, and approx. 20% of all tympanostomy tube procedures associated with recurrent otitis media. In addition, the vaccine may prevent approximately 20% of all x-ray diagnosed pneumonia cases.

Does the pneumococcal vaccine protect against meningitis caused by the meningococcal bacterium?
The pneumococcal vaccine does not protect against the meningococcal bacterium, which is the second most frequent cause of bacterial meningitis in Denmark.

How long does vaccination protect?
After a vaccination series, a child is considered to be protected against invasive pneumococcal disease caused by the seven pneumococcal types until the age of four. Above such age, invasive pneumococcal disease rarely occurs in children.

Which interval is required between two vaccinations?
Age 3-11 months at first vaccination:
The minimum interval between the first and second vaccination is one month.
The minimum interval between the second and third vaccination is two months.
The third vaccination should be administered when the child is at least 12 months old.
Age > 12 months at first vaccination:
Two vaccines are given at a minimum interval of two months.

Why should children above the age of 1 year only receive two vaccinations?
In children above the age of one year, the immune system has matured sufficiently to form adequate antibodies after two vaccinations.

Is revaccination needed?
Revaccination of healthy children who have received a full vaccination series is not recommended. In children above the age of two years with an increased risk of invasive pneumococcal disease, revaccination with the 23-valent polysaccharide vaccine is recommended in accordance with the guidelines from the Danish Paediatric Society, EPI-NEWS 11/07.

May the vaccine be given in conjunction with other vaccines?
Yes, PCV7 may be given in conjunction with e.g. the DTaP-IPV/Hib and MMR vaccines. The vaccines should always be given at separate injection sites.

Which adverse effects may be expected?
Fever and local reaction presenting redness, swelling and tenderness around the injection site are frequent effects. After vaccination irritability, vomiting, diarrhoea and reduced appetite are also seen.

Why should all children receive pneumococcal vaccination?
The objective of the vaccination programme is to protect individuals as well as populations. When more persons are vaccinated, fewer remain to transmit the infection. A small number of unvaccinated persons will be protected if only a sufficiently large proportion is vaccinated, as the bacteria will not be able to circulate in the population. This is called herd immunity.

Who should not be vaccinated?
Children who are allergic to the ingredients of the vaccine, including diphtheria toxoid.

What is the difference between the two vaccines against pneumococci?
The vaccine used in the childhood vaccination programme is a conjugated vaccine containing capsule material from seven types of pneumococci which frequently cause infection in infants. The vaccine can be given from the age of 2 months.
The other vaccine is a polysaccharide vaccine containing capsule material from 23 types of pneumococci. This vaccine is ineffective in children below the age of two but recommended for children above the age of two years who are at increased risk of invasive pneumococcal disease and for healthy persons above the age of 64 years for whom the vaccine covers more than 90% of all cases of invasive pneumococcal disease.

Are further pneumococcal vaccines in the pipeline?
Within the next years, conjugated 10- and 13-valent pneumococcal vaccines covering 82% and 91%, respectively, of all invasive pneumococcal cases in children below the age of five years are expected to be approved. Type-independent pneumococcal vaccines are still experimental.

Where do pneumococci occur?
Pneumococci (Streptococcus pneumoniae) occur naturally in the nose and throat of persons of all ages worldwide. Carrier frequency is highest in children and particularly in those who attend day care and in adults who have close contact to children.

How are pneumococci transmitted?
Pneumococci are transmitted from person to person by sneezing, coughing or through direct contact.

Which infections are caused by pneumococci?
Pneumococci frequently cause acute otitis media, sinusitis and pneumonia. The most serious forms of invasive pneumococcal disease are sepsis and meningitis.

How common is invasive pneumococcal disease?
The highest occurrence of invasive pneumococcal disease is found in children under the age of two years and in elderly persons above the age of 64 years.
In the period 2000-2005, the incidence among children below the age of two years was approx. 50 cases per 10^5 per year, which is approx. 2.5 times more frequent than in the total population. Invasive pneumococcal disease rarely occurs in older children and adults. In the same period, the incidence for elderly persons above the age of 64 years was approx. 70 per 10^5 per year.
(P. Valentiner-Branth, P.H. Andersen, A.H. Christiansen, L. Vestergaard, S. Glismann, Dept. of Epidemiology, J.J. Christensen, Z.B. Harboe, H.B. Konradsen, DBMP)

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The Danish childhood vaccination programme as per 1 October 2007					
3 months	**5 months**	**12 months**	**15 months**	**5 years**	**12 years**
DTaPIPV/Hib 1 PCV7-1	DTaPIPV/Hib 2 PCV7- 2	DTaPIPV/Hib 3 PCV7-3	MMR 1	DTaPIPV booster	MMR 2

Catch-up programme for the conjugated pneumococcal vaccine (PCV7) as per 1 October 2007									
Age at 1st vaccination	**Additional GP visit**	**5 months**	**Additional GP visit**	**Additional GP visit**	**12 months**	**Additional GP visit**	**15 months**	**Additional GP visit**	**Additional GP visit**
4 months	PCV7-1	PCV7-2			PCV7-3				
5 months		PCV7-1	PCV7-2		PCV7-3				
6-8 months			PCV7-1	PCV7-2	PCV7-3				
9-11 months				PCV7-1	PCV7-2		PCV7-3		
12 months					PCV7-1		PCV7-2		
13 months						PCV7-1	PCV7-2		
14-15 months							PCV7-1	PCV7-2	
≥16 months								PCV7-1	PCV7-2
Three vaccinations: A minimum of 1 month between 1st and 2nd vaccination and a minimum of 2 months between 2nd and 3rd vaccination **2 vaccinations: A minimum of 2 months between vaccinations**									

(Department of Epidemiology, 12 September 2007)