



HPV VACCINE IN THE CHILDHOOD VACCINATION PROGRAMME

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As from 1 January 2009, vaccination against human papilloma virus (HPV) will form part of the Danish childhood vaccination programme for girls born in 1996 or later. The vaccination offer applies to girls aged 12-14 years of age. 1 October 2008 will see the initiation of an introduction programme, see below. The Gardasil[®] vaccine prevents premalignant genital lesions, cancer of the cervix uteri and external venereal warts caused by infection with HPV types 6, 11, 16 and 18. A total of 70% of all cervical cancer cases are caused by HPV type 16 or 18, and 90% of all condyloma cases are caused by HPV type 6 or 11.

The vaccination programme

HPV vaccination is performed by the patient's GP.

A vaccination series comprises three doses of Gardasil[®] 0.5 ml administered at day 0 and after 2 and 6 months.

The minimum interval separating 1st and 2nd vaccination is a month, and the 2nd and 3rd vaccinations should be given at a minimum interval of three months.

If possible, all three vaccinations should be administered within a year, and if one vaccination is delayed, the next should be given as soon as possible.

Introduction programme

During the introduction period - until end 2010 - HPV vaccination will also be offered to all girls born in 1993, 1994 or 1995. Three vaccines are given at the intervals stated above.

Service codes

Specific administrative service codes have been created:

1. HPV vaccination = 8328
2. HPV vaccination = 8329
3. HPV vaccination = 8330

It is essential that the correct codes are used in connection with all vaccinations. The service codes constitute the foundation of the current Danish childhood vaccination database and will be used for the ongoing monitoring of vaccination coverage as from 1 October 2008.

HPV vaccine and injection

The vaccine contains virus-like protein particles from HPV types 6, 11, 16 and 18. The virus-like particles are produced in yeast cells using recombinant DNA technology and are adsorbed to aluminium hydroxyphosphate sulphate as adjuvant. The HPV vaccine does not contain

genetic material from the virus and therefore cannot infect cells or cause infection in the vaccinee.

The vaccine should be shaken well before use to maintain suspension. At delivery, the vaccine may appear as a clear liquid with a white precipitation. After thorough agitation, it becomes a cloudy, white liquid. The vaccine should be administered intramuscularly to the upper arm (deltoid area), and may be given in conjunction with other vaccinations including MMR. When more vaccinations are given simultaneously, they should be administered at separate injection sites.

Further information on the HPV vaccine is available at www.ssi.dk under "Products" (Danish language).

Adverse events

Mild fever and redness, swelling, itching and soreness at the injection site occur frequently. These reactions are considered harmless and transient.

Overdoses have not caused an increase in the frequency of adverse effects.

Studies have not established an increased occurrence of serious adverse effects for HPV vaccinees compared with placebo vaccinees.

Contraindications

The vaccination is contraindicated in patients with allergies to the active substances or the excipients.

HPV vaccination must be postponed in patients with acute conditions causing fever. An ordinary cold with no fever should not postpone vaccination.

Post vaccination protection

A protective effect of the vaccine has been observed during a minimum period of 5 years. The full duration of the protective effect and any need for further vaccination at a later stage are unknown.

The HPV vaccine only protects against conditions caused by HPV types 6, 11, 16 and 18. Relevant preventive measures against sexually transmitted diseases must therefore also be used after vaccination.

The HPV vaccine is not indicated for treatment of cancer, dysplastic lesions or venereal warts.

HPV vaccination does not replace routine screening for cervical cancer, which remains very important. The minimal antibody level that provides protection against HPV infection has not been established. In clinical trials more than 99% were

seropositive to the four types of HPV vaccine one month after administration of the third dose. Among vaccinees, the antibody levels were significantly higher and remained higher during long-term follow up than in placebo vaccinees who had previously had an HPV infection. The protective effect may be reduced in persons with a weakened immune defence due to a reduced antibody response.

Information

In September the National Board of Health will send an invitation to all the girls covered by the introduction programme and also forward information material to all medical practices and to the municipal health services.

By January 2009 another invitation will be sent to any girls born in 1996, covered by the childhood vaccination programme.

Furthermore, the National Board of Health will establish www.StopHPV.dk providing additional information on HPV vaccination, cervical cancer, venereal warts, etc.

At www.ssi.dk you will also find FAQs on HPV vaccination and diagnostics (Danish language).

Comment

Worldwide, a total of > 30 million doses of Gardasil[®] have been sold. As the vaccine is relatively new, the risk of adverse effects has been carefully monitored. Therefore, the American health authorities have recently examined 9,749 episodes of which 6% were classified as serious, but no causative relation to the vaccine was established. On the basis of the observed risk of adverse effects, it was concluded that the HPV vaccine is safe.

HPV vaccination should be monitored closely to gain knowledge of the long-term effects on disease occurrence, and follow-up studies may contribute to clarify if there is a need for further vaccination. Consequently, the SSI has been given the task of establishing a registry recording the administered HPV vaccines. This task will be integrated in the establishment of a comprehensive Danish vaccination register with data on all vaccines which is expected to be set up by 2011.

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Individually notifiable diseases

Number of notifications received in the Department of Epidemiology, SSI (2008 figures are preliminary)

Table 1	Week 34 2008	Cum. 2008 ¹⁾	Cum. 2007 ¹⁾
AIDS	2	22	36
Anthrax	0	0	0
Botulism	0	0	0
Cholera	0	1	0
Creutzfeldt-Jakob	0	6	12
Diphtheria	0	0	0
Food-borne diseases	10	436	381
of these, infected abroad	0	63	74
Gonorrhoea	6	241	244
Haemorrhagic fever	0	0	0
Hepatitis A	0	25	17
of these, infected abroad	0	8	7
Hepatitis B (acute)	0	12	17
Hepatitis B (chronic)	0	121	189
Hepatitis C (acute)	0	6	4
Hepatitis C (chronic)	1	260	250
HIV	0	149	185
Legionella pneumonia	3	77	65
of these, infected abroad	0	19	16
Leprosy	0	0	0
Leptospirosis	0	3	7
Measles	0	9	1
Meningococcal disease	0	36	53
of these, group B	0	16	30
of these, group C	0	9	16
of these, unspec. + other	0	11	7
Mumps	0	20	3
Neuroborreliosis	0	24	52
Ornithosis	0	2	7
Pertussis (children < 2 years)	5	72	46
Plague	0	0	0
Polio	0	0	0
Purulent meningitis			
Haemophilus influenzae	0	2	2
Listeria monocytogenes	0	1	7
Streptococcus pneumoniae	0	59	80
Other aethiology	0	16	10
Unknown aethiology	0	15	12
Under registration	3	17	-
Rabies	0	0	0
Rubella (congenital)	0	1	0
Rubella (during pregnancy)	0	0	0
Shigellosis	3	50	68
of these, infected abroad	0	35	25
Syphilis	3	79	61
Tetanus	0	1	0
Tuberculosis	0	254	267
Typhoid/paratyphoid fever	0	19	13
of these, infected abroad	0	14	12
Typhus exanthematicus	0	0	2
VTEC/HUS	1	93	107
of these, infected abroad	0	30	32

¹⁾ Cumulative number 2008 and in corresponding period 2007

Selected laboratory diagnosed infections

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

Table 2	Week 34 2008	Cum. 2008 ²⁾	Cum. 2007 ²⁾
Bordetella pertussis (all ages)	9	126	126
Gonococci	11	240	247
of these, females	2	49	37
of these, males	9	191	210
Listeria monocytogenes	0	33	34
Mycoplasma pneumoniae			
Resp. specimens ³⁾	1	49	258
Serum specimens ⁴⁾	3	62	307
Streptococci ⁵⁾			
Group A streptococci	0	108	84
Group B streptococci	0	80	66
Group C streptococci	1	12	16
Group G streptococci	1	92	84
S. pneumoniae	9	659	718
Table 3	Week 32 2008	Cum. 2008 ²⁾	Cum. 2007 ²⁾
MRSA	13	371	364
Pathogenic int. bacteria ⁶⁾			
Campylobacter	125	1813	2285
S. Enteritidis	51	287	309
S. Typhimurium	74	1158	190
Other zoon. salmonella	26	601	446
Yersinia enterocolitica	3		
Verocytotoxin- producing E. coli	4	191	167
Enteropathogenic E. coli	10	90	104
Enterotoxigenic E. coli	10	98	108
Enterotoxigenic E. coli	6	205	143

²⁾ Cumulative number 2008 and in corresponding period 2007

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