

SCHEDULES OF PREVENTION

Poland's National Vaccination Program is an essential element in the strategy of prevention of infectious diseases and their complications, here considered with a particular focus on combination vaccines and the need for the Program's further expansion

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The regulations and procedures governing the prevention and treatment of infections and infectious diseases in the Polish population are outlined in the act of 5 December 2008 (*Journal of Laws* 2008, No. 234, item 1570). The act also defines the regulations and procedures governing the recognition and monitoring of epidemics, prevention and management of epidemics in order to neutralize sources of infection, and elimination of routes of spread of infection. An important element of fighting infectious diseases is immunization of people at risk of infection (Art. 1). All individuals who stay in Poland for three months or longer are required to have the compulsory vaccinations (Art. 5). Before undergoing vaccinations recommended as part of the National Vaccination Program, the patient is examined by a medical professional (Chapter 4, art. 17). The abovementioned act as well as the act covering patient rights and the

Patients' Ombudsman (*Journal of Laws* 2009 No. 76, item 641) note that it is also the duty of the doctor administering the compulsory vaccinations to inform the patient of additional, recommended vaccinations. It is not permitted and unethical for doctors to refuse to administer vaccinations or to provide information which is not based on scientific facts.

The statement by the Polish Health Minister, dated 18 August 2011, lists the infectious diseases covered by the compulsory vaccination program and the people and populations required to undergo compulsory vaccinations. Infectious diseases covered by the program are hepatitis B, tuberculosis, diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b (Hib), measles, mumps, rubella, *Streptococcus pneumoniae*,¹ chicken pox,² and rabies.³

Compulsory vaccinations are administered according to the Vaccination Program announced by the State Sanitary Inspectorate for each given year. In the statement from 19 October 2015 (item 63), the

¹Only for risk groups.

²Only for risk groups and certain children.

³After being bitten by a dog or other animal.

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Chief Sanitary Inspector announced that the Vaccination Program for 2016 includes:

1. **compulsory vaccinations** – a vaccination schedule including:
 - compulsory vaccinations for children and adolescents according to age,
 - compulsory vaccinations for people at risk of specific infections,
 - post-exposure vaccinations,
2. **recommended vaccinations** – not funded by the Health Ministry's budget.

We will now examine each of these schedules in turn.

Compulsory vaccinations (financed by the Health Ministry's budget) for individuals or groups are administered following the Health Minister's recommendations. The **tuberculosis vaccine** is usually administered within a day of a baby's birth; if this needs to be postponed for any reason, it must be administered before the child's 15th birthday.

Compulsory vaccination against hepatitis B covers children up to 19 years of age, students at medical schools and other universities teaching medical subjects, people at a high risk of infection due to being in regular contact with individuals infected with hepatitis B, people infected with the hepatitis C virus, people with late-stage kidney disease with a glomerular filtration rate below 30 ml/min, and patients undergoing dialysis. Booster vaccinations are not generally administered to healthy individuals. Revaccination following basic immunization is indicated for patients with immunodeficiency, cancer patients undergoing immunosuppressive treatment, transplant patients and people with diabetes.

The **diphtheria, tetanus and pertussis** vaccine is administered as a combination DTP vaccine, spread over three doses during the child's first 12 months and followed by a booster vaccine during the second year. Children born before the 37th week of pregnancy or with a birth weight below 2500 g are given the acellular version of the vaccine, known as DTaP. When the child is six years old, they are given a booster dose of DTaP. Fourteen-year-olds are recommended to be inoculated with a vaccine with smaller concentrations of the diphtheria and pertussis components (dTAp). Nineteen-year-olds are recommended the tetanus and diphtheria vaccine (Td).

The **poliomyelitis vaccination** involves two doses of the inactive polio vaccine (IPV) given during the child's first 12 months. The final booster dose is administered when the child is between 16 and 18 months old. Since 1 April 2016, six-year-olds should



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only be given the polyvalent polio vaccine (types 1, 2 and 3 of the virus). This follows the strategy of the World Health Organization (WHO) whose key element is to call WHO member states to withdraw the trivalent oral live vaccine (tOPV), which had also been used in Poland.

Compulsory polio and tetanus vaccination covers children and adolescents aged between seven weeks and 19 years. Additionally, **compulsory tetanus vaccination** covers people who are at risk of infection following an injury.

Vaccination against *Haemophilus influenzae* type b is administered at the same time as doses of the DTP vaccine. The full vaccination schedule includes three doses of the basic vaccine given during the first year and a booster dose given the following year. The vaccination program for 2016 includes an alternative combination vaccine DTaP-IPV-Hib. The Pediatric Expert Team for the Vaccination Program (PET-VP) recommends that the separate DTaP, IPV and Hib vaccines (delivered as

***Streptococcus pneumoniae* infection** is administered to:

1. children aged between two months and five years with central nervous system disorders or injury resulting in the leakage of cerebrospinal fluid, children infected with HIV, children who have undergone a stem cell transplant, children who are awaiting or have undergone an organ transplant, and children who are awaiting or have undergone a cochlear implant,
2. children aged between two months and five years who have chronic heart disease, immunohematological disease including idiopathic thrombocytopenia, acute leukemia, lymphoma, hereditary spherocytosis, hereditary asplenia, spleen dysfunction, children who have undergone a splenectomy or immunosuppressive treatment, children with chronic kidney dysfunction and recurring nephrotic syndrome, primary immunodeficiency, metabolic disease including diabetes, and chronic pulmonary disease including asthma,
3. children aged between two and 12 months born before 37 weeks gestation or with a birth weight below 2500 g.

It is not permitted and unethical for doctors to refuse to administer vaccinations or to provide information which is not based on scientific facts

three injections) are replaced by a polyvalent five-in-one vaccine in all children. The vaccine is as safe and effective as DTaP; it is also delivered as a single injection, which further improves its safety. For six-year-olds, PET-VP does not recommend the diphtheria, tetanus and pertussis vaccine with smaller concentrations of the diphtheria and pertussis components (dTap). Using vaccines with a lower concentration of the pertussis antigen may exacerbate the already epidemiologically-adverse situation faced by whooping cough. The dTap vaccine should only be used in children over seven years of age who had previously not received a DTaP booster.

The **measles, mumps and rubella vaccine** is given to children and adolescents aged between 13 months and 19 years. Children are given the trivalent combined MMR vaccine when they are 13 or 15 months old, and a booster dose when they are ten years old. This program covers girls and boys.

Following the Health Minister's recommendation, **compulsory vaccination against invasive**

Streptococcus pneumoniae infections are one of the main causes of morbidity and mortality around the world. The highest morbidity and mortality presents in extreme age groups, including children aged two and under and adults aged over 65. Based on epidemiological data and its assessment of infection risk, WHO declared pneumococcal infection a major global public health problem, recommending the use of vaccines in all countries (WHO 2012).

The incidence of pneumococcal infection is seriously underestimated in Poland, therefore we should really be talking in terms of detection rates rather than infection rates. Data from the National Reference Centre for Diagnostics of Bacterial CNS Infections shows that for the PCV10 and PCV13 vaccines, during the 2009–2013 period the forecast coverage was 63.1% and 81.6% respectively, and 48.7% and 74.4% respectively in 2014.

Pneumococcal resistance to antibiotics is a very significant and escalating problem. In 2014, the PCV10 and PCV13 vaccines provided a theoretical coverage of infections caused by penicillin-resistant pneumococci of 67.2% and 89.8% respectively, 3rd generation cephalosporin-resistant pneumococci of 73.0% and 94.6% respectively, erythromycin-resistant pneumococci of 63.1% and 90.3% respectively, and multiple drug-resistant pneumococci of 68.0% and 93.8% respectively. Antibiotic resistance is a major issue which should encourage us to urgently in-

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roduce general pneumococcus vaccination to the most at-risk groups, including children under two years of age.

A seven-year vaccination program (including treatment with the PCV7 vaccine between 2006 and 2009, and the PCV13 vaccine between 2010 and 2012) carried out in the Polish city of Kielce has been a major success in the local community, confirming the benefits of vaccination. Conclusions from the program show a significant reduction in the number of hospitalizations due to pneumonia in all age groups (including people aged 50 and over who have not been vaccinated), a reduction in the number of carriers of vaccine strains, and a reduction in the numbers of carriers of penicillin-resistant strains.

Since 2007, the main priority of the changes proposed by the PET-VP team appointed by the Health Minister has been the introduction of the pneumococcus vaccine to the vaccination program covering all children aged two and under. Vaccinating all children against pneumococcal infection should be a national health priority; its high clinical effectiveness and low cost make it one of the most cost-efficient activities in public health. Currently, the pneumococcus vaccine is financed only for premature babies and children under five years of age who are at a high risk of infection.

Following the Health Minister's recommendation, **compulsory vaccination against chicken pox** covers children under 12 years of age who are immunosuppressed and therefore at risk of developing severe symptoms, children in remission from acute lymphoblastoma, children infected with HIV, children awaiting immunosuppressive treatment or chemotherapy, healthy adults in those children's environment who have not had chicken pox, children being cared for at children's homes and foster homes, and children attending nurseries and children's clubs.

Recommended vaccinations, not funded by the Health Ministry's budget, include those against:

1. viral hepatitis A,
2. flu (in children under five with primary and secondary immunodeficiency and certain

chronic illnesses, infection with the flu virus can present with unusually severe symptoms and it can have a higher than average mortality),

3. rotavirus,
4. invasive meningococcal infection (in Poland, the incidence of meningococcal infection is between 200 and 400 cases per year. The incidence is highest among children aged 12 months and below. The mortality rate ranges between 11% and 33%, with the highest mortality among young children and elderly patients. 63% of infections in Poland are caused by serogroup B meningococci and 30% by serogroup C meningococci. Young children are at the greatest risk of complications following meningococcal infection),
5. tick-borne encephalitis,
6. human papillomavirus (HPV), a major cause of cervical cancer.

Following the recommendations of the Polish Gynecological Society and the Polish Pediatric Society, **the HPV vaccine** should be administered to all girls aged 11 and 12, and those aged between 13 and 18 who have yet to receive the vaccine (catch-up vaccine).

Cervical cancer is a major public health issue. In 2012, the morbidity and mortality in Poland were 17.7 and 9.4 per 100,000, respectively. In 2010, 3078 new cases of invasive cervical cancer (C53) and *in situ* carcinomas (D06) were registered in Poland. Poland also has the lowest percentage of five-year survival rates of patients treated for cervical cancer. HPV infection can also be a causal factor for other cancers. Genital warts and the rare laryngeal papillomatosis are clinical symptoms of low oncogenic risk HPV infection. HPV types 6 and 11 are the cause of between 90% and 100% of genital warts in men and women. The development of effective vaccines against selected HPV strains has paved the way for new ways of preventing cervical cancer. The main aim of HPV vaccination is to prevent the development of precancerous lesions and cervical and anal cancer. Many countries have introduced HPV vaccination into their vaccination programs. There are three vaccines registered for the prevention of HPV infection: the 4- and 9-valent Silgard (MSD) and the bivalent Cervarix (GSK). The antigenic component of all these vaccines is the L1 protein, present as virus-like particles (VLP). This structure prevents the development of HPV infection following the administration of the vaccine. The vaccine has no effect on existing active HPV infection. Clinical studies have not shown the vaccine to be effective in the treatment of pathological changes of the cervix.

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