

Pneumococcal infections and vaccination - questions and answers

What causes pneumococcal infections or diseases?

Pneumococcal infections are caused by the bacterium *Streptococcus pneumoniae* (pneumococcus). There are more than 90 serotypes of this bacterium, most of which can cause disease.

How is the infection transmitted and who is at higher risk of contracting the disease?

Pneumococci can normally be present in the mucous membranes of the respiratory tract, especially in the nose and throat. They are transmitted between humans by infectious droplets produced when sneezing and coughing. In addition to the presence of the bacterium, reduced immunity is also important for the development of the disease. Young children, the elderly, people with chronic diseases and immunodeficiency are particularly at risk. The risk of pneumococcal disease is also increased by previous viral respiratory infections that weaken local immunity.

How long is a person with pneumococcal infection infectious?

The exact period of infectivity is unknown. It appears that transmission can occur as long as pneumococcus is present in respiratory secretions. Healthy carriers are more important than patients for the spread of pneumococcus.

What diseases can pneumococcus cause?

Pneumococcal pneumonia can cause sinusitis, otitis media, pneumonia, blood infections (bacteraemia, sepsis) and inflammation of the meninges (meningitis). Some serious pneumococcal infections (invasive pneumonia, sepsis, meningitis) can be fatal.

Otitis media is the most common pneumococcal infection in children. It presents with ear pain, a red and tense eardrum, ear discharge and fever, and in infants, irritability and diarrhoea.

Pneumococcal pneumonia can occur 1-3 days after infection. The illness starts suddenly and presents with chills, fever, cough with yellow purulent expectoration, sharp chest pain that worsens with deep inspiration, heavy and/or rapid breathing, increased heart rate and weakness. The mortality rate is 5–7%, and can be more than 50% in the elderly.

Sepsis is an infection of the blood that results in death in 4 out of 100 children. Mortality is even higher in the elderly.

Pneumococcal meningitis is characterised by headache, fatigue, vomiting, irritability, fever, stiff neck, neurological deficits, convulsions and coma. The mortality rate of patients with pneumococcal meningitis is around 10%. Neurological sequelae are common in survivors.

How common are invasive pneumococcal infections in Slovenia?

Pneumococcal infections are most common in children under 5 years of age and in older people (aged 65 years and older). Most infections are reported in children aged one year, at a rate of one in every 1,000 to 2,000 children per year. In other age groups, pneumococcal infections are less common. In Slovenia, 14 people died from invasive pneumococcal infections in 2021.

In Slovenia, the incidence of invasive pneumococcal infections is higher than in many European countries, where the rate of infection has fallen dramatically since the introduction of routine pneumococcal vaccination.

What is the treatment for pneumococcal infections?

Pneumococcal infections are treated with antibiotics. Recently, pneumococcal resistance to antibiotics has been emerging, which makes treatment more difficult. For this reason, it is important to follow the instructions of your doctor and pharmacist when taking antibiotics, and it is particularly important to prevent infections, especially through vaccination.

Can you get ill with pneumococcal infection more than once?

Yes. A history of infection with one of the 90 pneumococcal serotypes does not confer immunity to infection with the other serotypes. Vaccination is also recommended if the individual has had one or more episodes of invasive pneumococcal infection.

Is there a vaccine against pneumococcal infections?

Yes. Three types of pneumococcal vaccines are available: 13-valent and 20-valent conjugated vaccines and a 23-valent polysaccharide vaccine. All three vaccines are dead and prevent infection with the pneumococcal serotypes that most commonly cause invasive diseases.

What characterises a polysaccharide vaccine?

The first polysaccharide vaccine became available in the 1970s. The polysaccharide vaccine, which protects against 23 pneumococcal serotypes, has been available since the 1980s and is also available in Slovenia. It is intended to protect people aged 2 years and older at increased risk of invasive pneumococcal infection. These people with chronic diseases, especially chronic circulatory, respiratory, urinary and liver diseases, metabolic diseases (diabetes...), certain neuromuscular and connective diseases, malignancies, certain blood and haematopoietic diseases, and diseases and conditions weaken the immune response. The vaccine is also available to all people aged 65 and over.

What is specific to conjugated vaccines?

The first conjugated vaccine was made available in 2000. A conjugated vaccine against 13 pneumococcal serotypes (13-valent vaccine) has been available in Slovenia since 2010, and a conjugated vaccine against 20 pneumococcal serotypes (20-valent vaccine) since 2023. Conjugated vaccines stimulate a better immune response than the polysaccharide vaccine, and the 13-valent vaccine is also designed to protect infants and young children and can therefore be used for routine childhood vaccination.

The 13-valent conjugated vaccine is intended to prevent invasive diseases, pneumonias and acute otitis media caused by pneumococcus in infants, children and adolescents aged 6 weeks to 17 years, while the 13-valent and 20-valent conjugated vaccines are also intended to prevent invasive diseases and pneumonias caused by pneumococcus in adults aged 18 years and older.

Do pneumococcal vaccines contain aluminium?

The pneumococcal conjugated vaccines (13-valent and 20-valent vaccines) contain a small amount of aluminium salt (aluminium phosphate), which is important for a better immune response to the vaccine. Pneumococcal polysaccharide vaccine (23-valent vaccine) does not contain aluminium.

Aluminium is one of the most widespread metals in our environment. It is found in water, air, food, cosmetics, medicines and even breast milk. The main source of aluminium that is taken into the body is food. Aluminium has been used in vaccines as an immune response enhancer (adjuvant) for more than 70 years. Administration of a dose of the vaccine into the muscle does not cause detectable changes in the blood aluminium concentration. Almost all of the aluminium is rapidly eliminated from the body.

Do pneumococcal vaccines contain thimerosal?

No.

What is the routine vaccination scheme for children against pneumococcal infections?

Children are routinely vaccinated with a conjugated vaccine.

Childhood vaccination starts at 3 months of age, at the same time as the hexavalent vaccine (against diphtheria, tetanus, whooping cough, Haemophilus influenzae type b, polio and hepatitis B). The second dose is given to children together with the second dose of the hexavalent vaccine at 5 months of age. The third dose is given between 11 and 18 months of age.

Can I wait to vaccinate until my child is one year old?

Children most commonly contract invasive pneumococcal diseases in their second year of age in Slovenia, followed by children under one year of age. Therefore, the greatest advantage in preventing these infections through vaccination is gained by vaccinating children at the recommended age and not delaying vaccination.

What are other childhood immunisation schemes?

Children with chronic circulatory, respiratory, liver, kidney diseases, spleen absence, diabetes, cochlear implants, certain nerve and muscle diseases and conditions that weaken the immune response are at higher risk of a more severe course of pneumococcal disease. In addition to the conjugated vaccine, a single dose of the polysaccharide vaccine is recommended for them when they reach 2 years of age, at least 2 months after the last dose of the conjugated vaccine.

What are the vaccination schemes for children over 5 years and adults?

Vaccination against pneumococcal infections is not routinely recommended for healthy persons between 5 and 64 years of age, but is possible with a single dose of vaccine. Vaccination against pneumococcal infections is recommended for people aged 65 years and older and for chronic patients, as they are at higher risk of developing invasive pneumococcal infections. For children over 5 years and adults, the recommendations in the flowchart at the following link apply.

How is the vaccine administered?

The pneumococcal vaccine is administered to children under two years of age by pricking the muscle on the front of the thigh. In children over two years of age, the vaccine is administered by pricking the muscle or subcutaneous tissue of the upper arm, depending on the type of vaccine.

Who recommends vaccination against pneumococcal infections?

Vaccination against pneumococcal infections is recommended by the National Institute of Public Health (NIJZ), the Vaccination Advisory Group, the Association of Paediatrics of the Slovenian Medical Association (SZD), the Department of infectious diseases of the UKC Ljubljana, the European Centre for Disease Prevention and Control (ECDC), the World Health Organisation (WHO), and many other professional associations both domestic and foreign.

How effective are the vaccines against pneumococcal infections?

Vaccines against pneumococcal infections have been shown to be effective in clinical trials.

The effectiveness of the 7-valent conjugated vaccine (the precursor to the 13-valent vaccine) was studied in almost 38,000 children. Half of the children received the 7-valent vaccine and half received

the control vaccine, which was not effective against pneumococcal pneumonia. During 3.5 years of follow-up, 3 cases of invasive pneumococcal infections were detected in children vaccinated with the 7-valent vaccine and 49 cases in children vaccinated with the control vaccine. Additional research has shown that the 7-valent vaccine is safe and effective in children up to 5 years of age.

Research has shown that the immune response to the 13-valent conjugated vaccine in children is at least as good as that to the 7-valent vaccine. Additional research showed that the 13-valent vaccine increased the immune response after the booster dose, supporting a switch to the 13-valent vaccine in children initially vaccinated with the 7-valent vaccine. The 13-valent vaccine also had no effect on the immune response to other vaccines routinely given to children.

Research has also shown that the immune response to the 13-valent conjugated vaccine is at least as good as that to the 23-valent polysaccharide vaccine in adults (for all 12 serotypes common to the two vaccines), and even better against some pneumococcal serotypes.

Studies have shown that the immune response to the 20-valent conjugated vaccine in people aged 60 years or older is also good compared to the 13-valent conjugated vaccine. Studies have also shown that the immune response to the 20-valent conjugated vaccine is at least as good or better in people aged 60 years or older than to the 23-valent polysaccharide vaccine (for 6 of the 7 additional serotypes common to the two vaccines). The immune response to the 20-valent conjugated vaccine (for all 20 serotypes) was also good in subjects aged 18–59 years.

23-valent pneumococcal polysaccharide vaccine is 50–80% effective in preventing invasive pneumococcal disease. In older people (65 years and older) and those with significant co-morbidities, the effectiveness is slightly lower, but vaccination is still recommended because these people are at high risk of developing invasive pneumococcal infection.

How safe are vaccines against pneumococcal infections?

Vaccines against pneumococcal infections have been shown to be safe in clinical trials. The risk of complications from the disease is significantly higher than the risk of serious side effects after vaccination.

The most commonly reported symptoms after vaccination with pneumococcal vaccines were local injection site reactions (redness, pain, and swelling), fever, muscle and joint pain, headache, temporary loss of appetite, irritability, restless sleep, fatigue and drowsiness, vomiting, diarrhoea and rash. Side effects that are more serious have been rare.

Adverse reactions to vaccination with pneumococcal vaccines are regularly monitored by public health authorities (in Slovenia, reports are collected by the Register of Adverse Reactions after Vaccination at the NIJZ), the Slovenian Public Agency for Medicinal Products and Medical Devices, the European Medicines Agency and manufacturers.

Can the vaccine cause pneumococcal infection?

No. All available pneumococcal vaccines are dead and contain only purified particles of the microbe, so they cannot cause pneumococcal infection.

Can a pregnant or breastfeeding woman receive the pneumococcal vaccine? How does the vaccine affect fertility?

No data are available on the effect of the 13-valent conjugated vaccine on pregnancy, so for the time being the recommendation is not to vaccinate pregnant women with this vaccine. There are no data

on the use of the 20-valent vaccine in pregnant women; administration of this vaccine during pregnancy should only be considered if the potential benefits outweigh any potential risks to mother and foetus. It is not known whether the 13-valent or the 20-valent conjugated vaccine is excreted in the milk of breastfeeding mothers. Animal studies show that the vaccines have no adverse effect on fertility.

There have been reports of a number of pregnant women who have received the polysaccharide pneumococcal vaccine without adverse effects on the foetus, but there is not yet enough data on the effect of this vaccine on pregnancy. The recommendation is not to vaccinate pregnant women with this vaccine unless there is a high risk of infection. Women at high risk of invasive pneumococcal infection should be vaccinated before becoming pregnant if possible. Unvaccinated pregnant women at high risk should consult their doctor about possible vaccination. The polysaccharide vaccine can be used in breastfeeding mothers.

Who should not receive the vaccine against pneumococcal infections?

Persons who have had a severe allergic (anaphylactic) reaction after a previous dose of the same vaccine or who are severely allergic to any of the vaccine components should not be vaccinated against pneumococcal infections. If a person is moderately or seriously ill with fever, vaccination is temporarily delayed until recovery. People with mild illness (e.g. cold) can be vaccinated.