For influenza vaccination of children and adolescents with live vaccine (nasal spray)

Acute respiratory diseases are among the most frequent diseases in humans. They are caused by a variety of pathogens, in particular by viruses. The influenza virus, the causative agent of the 'real' flu, plays a central role. The special role of influenza is due to its epidemic occurrence each year. In addition, influenza viruses usually cause a more severe course of disease than other pathogens responsible for acute respiratory diseases.

The best protection is timely vaccination. Influenza vaccination does not protect against acute respiratory diseases caused by other pathogens that typically have a mild course.

Influenza is an acute respiratory illness accompanied by fever, cough, and muscle pains; it cannot always be clinically distinguished from other respiratory diseases. Especially in the chronically ill, severe courses of influenza are often observed. Viral flu occurs more frequently in the cold season. Vaccinations should therefore generally be given during the fall months. However, the protective vaccination can be given at any time. Influenza viruses are constantly changing, so that even people who were afflicted by influenza the previous year or were vaccinated may fall ill with influenza again the next year. The influenza vaccination must therefore be repeated with a current vaccine each year.

Vaccine

The influenza vaccine is produced each year according to the current recommendation by the World Health Organization (WHO); it is a so-called seasonal vaccine. The recommendation takes into account the currently globally circulating influenza viruses of types A and B. The quadrivalent live vaccine contains components of two influenza-A-viruses and of two influenza-B-viruses, which often appear at the same time. In larger intervals, there is the danger of the worldwide spread of a completely new influenza pathogen (pandemic). After 2009, this was the case with the “new influenza A/H1N1,” also sometimes referred to as “swine flu.” However, this new pathogen has meanwhile displaced the previously circulating influenza A/H1N1 viruses and is therefore included as one of the components of the current seasonal influenza vaccine.

In addition to the inactivated influenza vaccines that have been approved for years in children and adolescents, a live vaccine is now available for children and adolescents ages 2 through 17 years. This vaccine contains weakened live influenza viruses that propagate in the nasopharynx area and thereby create protective immunity. The vaccine must be used only as a nasal spray and is administered in both nostrils. Breathing can be continued normally during this procedure. It is not necessary to actively breathe through the nose. The vaccine must not be injected under any circumstances.

The vaccination may be given together with other live virus vaccines, such as against measles, mumps, rubella, and varicella. The vaccination does not need to be spaced apart from other vaccinations that are required in the context of the immunization calendar for children. The vaccination consists of one vaccine dose; children who were not vaccinated against influenza previously receive 2 doses spaced at least 4 weeks apart. The vaccination protection starts approximately 2 weeks after vaccination.
It is recommended not to administer the vaccine together with flu-specific, antiviral medicines (e.g. neuraminidase inhibitors).

**Who should be vaccinated?**
As of August 2013, the Standing Committee on Vaccinations recommends preferably using the live vaccine in children ages 2 through 6 years. Good tolerability in children and adolescents with mild to moderate asthma is proven, however, to date there is only limited data on children with other pulmonary diseases, or chronic cardiovascular-, metabolic- or renal disease. Influenza vaccination is recommended for children and adolescents who are particular vulnerable to influenza (for contra-indications, see "who should not be vaccinated"), for example, patients with chronic respiratory diseases, chronic cardiovascular-, liver- and kidney diseases, metabolic diseases (e.g. diabetes), asymptomatic HIV infection, and chronic neurological diseases. People who could infect particularly vulnerable people should also be vaccinated.

**Who should not be vaccinated?**
People suffering from an acute illness with fever that requires treatment should not be vaccinated. People with known severe hypersensitivity (allergy) to components of the vaccine (chicken protein, gelatin or gentamicin) must also not be vaccinated with this vaccine; likewise, children and adolescents with a compromised immune system due to diseases or as a result of immunosuppressive therapy (e.g. chemotherapy or high-dose cortisone therapy). Children and adolescents with severe asthma, or whistling breathing (acute wheezing) should not receive the live vaccine. Infants and toddlers ages 2 years and younger must not be immunized with the nasal spray. Like with all live vaccines, administration of the live influenza vaccine is not recommended during pregnancy. The vaccine should also not be used during breast-feeding. There is also the risk that vaccinated persons could transfer influenza viruses to immunocompromised people.

**Care after vaccination**
The vaccinated person does not require special care, but within 3 days after the vaccination unusual physical stress should be avoided. People with known immediate allergic responses should tell the doctor before getting vaccinated. Up to 4 weeks after the vaccination, vaccinated people should not take salicylates (in analgesics and fever-reducing drugs.) There is a risk of a very rare disease (Reye’s Syndrome).

**Possible local- and systemic reactions after vaccination**
After vaccination, in addition to the desired immunity and thus protection against the disease, several general symptoms may occur, which usually appear within 1 to 3 days, rarely for a longer time. These commonly include (up to 10 %): runny and stuffy nose, decreased appetite, and headache; common (between 1-10 %): fever and muscle pain; occasionally (between 0.1 -1 % ): nose bleeds, and skin rash. In general, the mentioned reactions are temporary, local and general responses, and they quickly subside without consequences.
Are complications from the vaccine possible?
Vaccine-associated complications are very rare consequences beyond the normal vaccination response that significantly affect the health of the person who received the vaccine. After an influenza vaccination, hypersensitivity reactions are occasionally seen, e.g. of the skin (itching and hives) as well as swelling of the face, very rarely to shock. In isolated cases, nervous system disorders (neuritis, temporary paralysis) have been described and exacerbation of symptoms of the very rare Leigh syndrome (congenital enzyme deficiency with involvement of the brain).

Advice by the vaccination administrator on possible side effects
In addition to this information sheet, your doctor offers a consultation. If symptoms appear after vaccination that are beyond the above-mentioned quickly subsiding local and systemic reactions, your vaccination administrator will of course also be available for consultation.

You can contact the vaccination administrator at:

Disclaimer

The original information sheet (version: 10/2014) was translated with kind permission by Deutsches Grünes Kreuz e.V [German Green Cross e.V] on behalf of the Robert-Koch-Institute. The German text is binding. Liability cannot be assumed for potential translation errors or for the currentness of the present translation in the event subsequent revisions are made to the German original.
Vaccination against influenza with live vaccine (nasal spray)
Schutzimpfung gegen Influenza mit Lebendimpfstoff (Nasenspray)

Please find enclosed an information sheet that describes how the vaccination against influenza is given. It contains the relevant information about the disease that can be prevented by the vaccine, about the vaccine, about the vaccination, vaccination reactions and possible vaccination complications.

Anliegend erhalten Sie ein Merkblatt über die Durchführung der Schutzimpfung gegen Influenza. Darin sind die wesentlichen Angaben über die durch die Impfung vermeidbare Krankheit, den Impfstoff, die Impfung sowie über Impfreaktionen und mögliche Impfkomplikationen enthalten.

Before the vaccination is given, the following additional information is requested:

Vor der Durchführung der Impfung wird zusätzlich um folgende Angaben gebeten:

1. Does the person to be vaccinated have an immunodeficiency (acquired, congenital, due by medication)?
   Besteht bei dem Impfling eine Immunmangelkrankheit (erworben, angeboren, durch Medikamente bedingt)?
   □ Yes (Ja)  □ No (Nein)

2. Did the person to be vaccinated receive immunoglobulin (gamma globulin) or a blood transfusion within the past three months?
   Hat der Impfling in den vergangenen drei Monaten Immunglobulin (Gammaglobulin) erhalten oder wurde eine Bluttransfusion vorgenommen?
   □ Yes (Ja)  □ No (Nein)

3. Does the patient have a known allergy - in particular against chicken protein?
   Ist bei dem Patienten eine Allergie – insbesondere gegen Hühnereiweiß – bekannt?
   □ Yes (Ja)  □ No (Nein)
   If yes, which________________________________________________________
   wenn ja, welche

4. Did the person receiving the vaccination have allergic responses, high fever, or other abnormal reactions after a previous vaccination?
   Traten bei dem Impfling nach einer früheren Impfung allergische Erscheinungen, hohes Fieber oder andere ungewöhnliche Reaktionen auf?
   □ Yes (Ja)  □ No (Nein)

If you would like to know more about the vaccination against influenza, ask the vaccination administrator!
Falls Sie noch mehr über die Schutzimpfung gegen Influenza wissen wollen, fragen Sie den Impfarzt!

Please bring your immunization record card with you to the immunization appointment.
Zum Impftermin bringen Sie bitte das Impfbuch mit!
Consent Form
Einverständniserklärung

for vaccination against influenza - with a live vaccine
zur Durchführung der Schutzimpfung gegen Influenza – mit Lebendimpfstoff

Name of person to be vaccinated
Name des Impflings

Born on
gen. am

I have read the content of the information sheet and have had my doctor explain the vaccination to me in detail.
Ich habe den Inhalt des Merkblatts zur Kenntnis genommen und bin von meinem Arzt/meiner Ärztin im Gespräch ausführlich über die Impfung aufgeklärt worden.

☐ I have no further questions.
   Ich habe keine weiteren Fragen.

☐ I agree to the proposed vaccination against influenza.
   Ich willige in die vorgeschlagene Impfung gegen Influenza ein.

☐ I decline the vaccination. I was informed about possible disadvantages of declining this vaccination.
   Ich lehne die Impfung ab. Über mögliche Nachteile der Ablehnung dieser Impfung wurde ich informiert.

Comments
Vermerke

Place, Date
Ort, Datum

Signature of the person receiving the vaccination, or guardian
Unterschrift des Impflings bzw. des Sorgeberechtigten

Signature of the doctor
Unterschrift des Arztes/der Ärztin