Informative factsheet on vaccination against the novel A/(H1N1) influenza

The respiratory illness caused by the novel pandemic influenza A/(H1N1) virus is often accompanied by the sudden onset of symptoms. The most frequent symptoms mimic those of the yearly seasonal influenza and include **fever, cough, headache and muscle aches, fatigue and loss of appetite**. Some persons have reported nausea, vomiting and diarrhoea. At present, the novel flu is, in the majority of cases, a self-limiting disease that is no more severe than the 'normal' seasonal flu. Chronic conditions such as respiratory illness, cardiovascular disease, diabetes or pregnancy may sharply increase the severity of the disease. Unlike with the seasonal flu, young persons are also seriously affected at a disproportionate rate.

The incubation period of the novel flu A/(H1N1) virus seems to be similar to that of the seasonal flu. People can infect others shortly (less than 24 hours) before they notice the first symptoms and from then on up to one week.

According to current knowledge, vaccination against seasonal influenza does not protect against the novel A/H1N1 influenza .

The vaccine

Specific vaccines have been developed to protect against the novel influenza A/(H1N1) virus. The vaccines used are inactivated vaccines (inoculation with killed virus) against the pandemic virus strain. The licensing and use of vaccines against the novel A/(H1N1) influenza is based on decades of experience with seasonal flu vaccines as well as on clinical studies with 'mock-up' pandemic influenza vaccines containing the antigen to the avian H5N1 influenza.

These studies have shown that two flu shots build up a sufficient immune response. However, studies using the vaccines against influenza A/H1N1 provide initial evidence that persons between the ages of 10 and 60 years might only need a single shot to trigger a proper immune response. Therefore, this age group is currently scheduled to receive only one shot. As soon as additional clinical studies are evaluated (by mid-November 2009), it will be decided whether or not a second shot is recommended.

A special feature of the vaccine against the novel A/(H1N1) flu is the use of immune-boosting additives (adjuvants) on an oil-in-water basis. These additives boost the body's immune response and provide a broader range of protection in case of virus mutations.

The Standing Committee on Vaccination (*Ständige Impfkommission - STIKO*) recommends, pending the availability of additional data, that pregnant women be vaccinated with an unadjuvanted vaccine. However, pregnancy is not a counter-indication for immunisation with an adjuvanted vaccine (such as "Pandemrix"). After individual counselling, therefore, pregnant women may, particularly in the presence of special risks (such as underlying chronic disease, elevated risk of infection) be vaccinated with an adjuvanted vaccine if no other vaccine is available.

Who should not be vaccinated?

Vaccinations should, in principle, be preceded by an individual benefit-risk evaluation. This goes particularly for chronically ill persons, children and pregnant women for whom only few or no data from clinical trials are as yet available.

Persons suffering from an acute **feverish illness** that requires medical attention should not be vaccinated. These persons should thereafter seek vaccination at the earliest possible date.

Persons suffering from a proven **allergy** to chicken ovalbumin (egg white) should not be vaccinated with a vaccine incubated in chicken eggs. Nor may persons with a history of intense hypersensitivity to trace quantities of residual substances, such as thimerosal, formaldehyde, gentamycin sulphate, sodium deoxycholate, be vaccinated either.

Possible vaccination side effects (see also technical information "Pandemrix")

The vaccine is generally well tolerated. Due to the addition of immune boosters (adjuvants), however, local or general reactions are somewhat more likely than with seasonal flu vaccines. Reactions include:

Redness and painful swelling at the injection site as well as headache, fever, fatigue, joint and muscle pain. Frequently (≥1/100 to <1/10 cases), swelling of lymph nodes, pruritus or hemorrhages at the injection site, more intense sweating, chills or flu-like symptoms can occur. Occasionally (≥1/1,000 to <1/100 cases), general symptoms such as shivering, drowsiness, numbness of the hands and feet, somnolence, insomnia, nausea, eczema, vertigo, general malaise, vomiting or abdominal pain have been observed.

Side effects are often signs of the body's normal response to the vaccine. In most cases, the above-mentioned local and general reactions are only transitory and resolve without sequelae. Rare and very rare side effects cannot be identified in clinical studies.
Observational studies have shown seasonal flu vaccines to cause, in very rare instances, allergic reactions of the dermal and bronchial systems; immediate allergic responses (anaphylactic shock) were only reported in isolated instances.
Equally rare responses are vasculitis or a transitory decrease in the blood platelets that are vital for blood clotting which may lead to hemorrhages.
The Guillain-Barré syndrome or other nervous lesions (such as nervous inflammations or nerve diseases) have only been observed in isolated instances following seasonal influenza immunisation.

Questionnaire and declaration of consent to the vaccination against the novel A/(H1N1) influenza

The foregoing information contains the essential details about this vaccine-preventable disease, the vaccine itself, vaccination, vaccination reactions and possible post-vaccination complications.

Before proceeding with the vaccination, please answer the following questions:

1.) Do you feel well at present?

Yes ☐ no ☐

2.) Do you have a known allergy?

Yes ☐ no ☐

If yes, to what? _____

3.) Have you ever had allergic symptoms, high fever or other unusual reactions after a vaccination?

Yes ☐ no ☐

If yes, which? _____

4. Are you pregnant?

Yes ☐ no ☐

5. Are you taking any medication?

Yes ☐ no ☐

If yes, which? _____

Declaration of consent

to the vaccination against the novel A/(H1N1) influenza

Name of the person to be vaccinated:

Date of birth:

I have read and understood this factsheet. I have also been made aware of the possibility of asking the vaccinating physician any further questions I might have.

☐ I have no further questions

☐ I did have further questions, but they have been answered

☐ I consent to the proposed vaccination against the novel influenza A/(H1N1)

Notes:

_____

_____

Place, date:_____

_____ _____

Signature of vaccinee or guardian

Signature of the informing physician