EPI-NEWS

NATIONAL SURVEILLANCE OF COMMUNICABLE DISEASES

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FAQs ON PANDEMIC VACCINE (PANDEMRIX®)

No. 43, 2009

As from week 45 physicians in general practice are expected to initiate vaccination against influenza A (H1N1)v using Pandemrix®. Practical information concerning vaccination was sent to GPs by the National Board of Health at the beginning of October and further information is available in EPI-NEWS 41/09, at www.sst.dk, and at www.ssi.dk (Danish language) In the below text, we answer a series of frequently asked questions in this context.
More questions are continually being answered at www.ssi.dk (Danish language). As from week 45, physicians and other health professionals may call +45 32 68 30 37 with any queries concerning the pandemic vaccine. The service is active on all work days until 6 pm.
Furthermore, the National Board of Health has set up a hotline covering general requests on influenza A (H1N1)v, including questions on risk groups and the pandemic guideline. The hotline is active throughout the opening hours of the National Board of Health: +45 72 22 85 22.
The Danish Medicines Agency may be contacted for queries concerning adverse events: +45 44 88 97 57 or bivirkninger@dkma.dk

Why is vaccination not recommended for everyone?
On the basis of current knowledge on new influenza A (H1N1)v, the National Board of Health estimates that the overwhelming majority of those who become infected will experience a mild disease course. Vaccination against influenza is primarily given with a view to prophylaxis against severe influenza illness or its complications.
Risk group persons are at increased risk of experiencing a more severe disease course when infected with influenza A (H1N1)v. Consequently, risk group persons, as defined by the National Board of Health, EPI-NEWS 41/09 and any nursing staff who may come in to contact with such persons should receive vaccination.

SPECIAL GROUPS

Does the foetus obtain protection if a pregnant woman is vaccinated?
There are no studies to demonstrate if this is the case, but is possible that the foetus may achieve some degree of protection from the vaccination of the child-bearing woman.

Lactating women and vaccination
Pandemrix® is approved for administration to lactating women.

Should immunosuppressed individuals receive vaccination?
Patients with congenital as well as acquired immunodefiencies including splenectomised, HIV-infected and pharmacologically immunosuppressed patients should receive vaccination due to the increased risk of serious disease associated with influenza infection.
When possible, vaccination should take place three weeks prior to initiation of immunosuppressive therapy.

Who should not be vaccinated?
Persons with type 1 allergy to the excipients, e.g. egg and chicken protein, formaldehyde and gentamicin, should not be vaccinated.
As is the case with other vaccines, vaccination should be postponed in case of acute illness or fever.

May persons with allergic contact dermatitis be vaccinated?
Allergy to the excipient formaldehyde will frequently manifest as contact dermatitis. This does not constitute a contraindication, and the risk may be reduced by ensuring intramuscular vaccination.

Should persons who have had influenza this year be vaccinated?
Persons who have had laboratory-confirmed new influenza A (H1N1)v will not benefit from receiving the pandemic vaccine (but may be vaccinated against seasonal influenza).
Persons who have had influenza-like disease which was not confirmed as influenza A (H1N1)v should be vaccinated provided they belong to a risk group. (There is no need to test for antibodies prior to such vaccination).

Is influenza vaccination required for pilgrimage to Mecca?
Pandemic vaccination is not a visa requirement for persons going on pilgrimage to Mecca. The Saudi Arabian health authorities recommend vaccination against seasonal as well as pandemic influenza when such vaccination is available. In Denmark, only persons comprised by the recommendations from the National Board of Health will be eligible for pandemic vaccination.

THE VACCINE

What does the pandemic vaccine contain?
The antigen is a surface protein (haemagglutinin) purified from inactivated influenza virus after culture in unfertilised eggs.
The pandemic vaccine furthermore contains an excipient (adjuvant AS03) which consists of squalene (an oil present in plants and animals), DL-alpha tocopherol (Vitamin E1) and emulsifier (polysorbate 80).
Furthermore, the vaccine contains the preservative thiomersal. An adult vaccine dose contains 5 micrograms of thiomersal, corresponding to 2.5 micrograms of ethylmercury.

Does the vaccine contain live virus?
No. Consequently, it cannot cause influenza illness.

Why does the vaccine contain exipients (adjuvants)?
The adjuvant AS03 has been added to increase the efficacy. The immune system's antibody response is improved, leading to a longer lasting and better protection and may also provide broader coverage against any influenza virus alterations. The use of adjuvants also reduces the amount of antigen needed.

Why does the vaccine contain thiomersal?
The vaccine is supplied in vials containing ten doses which are not always used immediately after suspension and first use. Contamination may occur during handling and therefore the preservative thiomersal has been added to the vaccine.

What is thiomersal?
Thiomersal contains an organomercuric compound (ethylmercury) different from the one ingested with a normal diet (methylmercury). The two mercury compounds are eliminated from the body in different ways, and they also differ with regard to the extent to which they are absorbed in brain tissue and by the extent to which they are degraded to inorganic mercury.

Does the amount of thiomersal contained in the vaccine comprise a health risk?
Thiomersal has been used in vaccines for about 60 years. It is estimated that several billion vaccine doses containing thiomersal have been administered worldwide. There is no documentation that thiomersal, applied in the doses contained in the vaccine, comprises a health risk to those vaccinated.

(SEE OVERLEAF)

Continued…
The substance is approved for use as a preservative in vaccines by pharmaceutical authorities worldwide and by the WHO.
The quantity contained in a dose of Pandemrix® (2.5 micrograms per adult dose) is considerably smaller than the amount of mercury you normally ingest with your food in a week.

Have threshold values been established for the intake of mercury via food?
A group of experts of the UN's Food and Agriculture Organization (FAO) and WHO have estimated that a weekly intake of mercury corresponding to 1.6 micrograms per kilo body weight is acceptable. Such level is thought to be safe even for the more vulnerable, i.e. pregnant women and foetuses.
The approved threshold values for mercury (methylmercury) in e.g. children's food is 50 micrograms per kilo and for fish it is 500 micrograms per kilo. Consequently, the ethylmercury content of Pandemrix® is many fold less than the methylmercury amounts allowed in foodstuffs.

How was the vaccine tested?
The pandemic vaccine was tested using H5N1 (avian influenza antigen) in a series of studies comprising approx. 12,000 persons and it has been found to be safe and effective. Pandemrix® is the same vaccine, the only difference is that the antigen used is H1N1v. The same principle of production is used every year in the production of the seasonal vaccine.
Several major studies are underway, and the results from these will be included in the continual assessments and recommendations made by the Danish authorities as they are published.

Is the pandemic vaccine effective against new influenza A H1N1v?
The vaccine is expected to provide a very high degree of protection against the new influenza.
The degree of protection is expected to be highest among persons with an intact immune response and less effective in persons with a weakened immune response.
The vaccine is expected to prevent a total of 70-90% of all disease cases among young, healthy persons. In the elderly, the degree of protection will be more limited.
If the influenza virus A H1N1v changes much during the epidemic, the protection may diminish or cease to exist.

How long does the vaccine protect?
There are no data on the long-term coverage of the pandemic vaccine, but studies on this issue are being planned.

Does the vaccine have side effects?
Like other vaccines the pandemic vaccine can be associated with side effects. The most frequent side effects are soreness, redness and swelling at the vaccination site, muscle and joint pains, headache and fever within 1-2 days after the vaccination. The side effects generally recede within 1-3 days.
These side effects are expected and harmless. In comparison with the ordinary influenza vaccine they are expected to occur somewhat more frequently.
Serious side effects are expected to occur very rarely. As is usually the case in connection with the introduction of new vaccines, the Danish Medicines Agency will ensure that comprehensive monitoring is established and that any serious side effects are assessed. If injury is caused by vaccination, the Danish Patient Insurance will pay damages in accordance with standard provisions.

How should presumed side effects of Pandemrix® be reported?
All presumed side effects after vaccination with Pandemrix® should be reported to the Danish Medicines Agency on the special vaccine form found at www.meldenbivirkning.dk (Danish language). Remember to state the vaccine's batch number when filling-in the form.

What is a serious adverse event?
An adverse event is serious if it:
- causes death
- is life-threatening
- calls for hospitalisation or continuation of previous admission to hospital
- causes extended or substantial disability or incapacity
- entails congenital malformation or congenital anomaly.

What is an unexpected adverse event?
An adverse event is unexpected if it: is not stated in the summary of product characteristics for Pandemrix®, see www.produktresume.dk (Danish language).

HANDLING OF THE VACCINE
Pandemrix® is to be administered intramuscularly.

What interval should there be from the first to the second Pandemrix® vaccine?
The first and second Pandemrix® vaccine should be administered at a 3-week interval at a minimum.

May the Pandemrix® vaccine be given in conjunction with other vaccines?
Pandemrix® may be given in conjunction with the seasonal influenza vaccine and other vaccines. Administration in conjunction with other vaccines probably increases the risk of side effects. Separate injection sites on opposite extremities should be used.

Is an interval needed with respect to other vaccines when these are not administered in conjunction with Pandemrix®
No, vaccination with other vaccines may be given in conjunction or at any interval with respect to Pandemrix®.

Practical handling before vaccination
Pandemrix® is supplied to the physicians who will administer it in packages containing two types of vials: suspension with antigen and emulsion with adjuvant. Prior to administration, the solutions should be kept at room temperature, shaken and mixed. This produces a whitish multi-dose vaccine corresponding to ten adult doses. This solution should be shaken before every dose withdrawal and administration.
Also see the summary of product characteristics at www.produktresume.dk (Danish language).

How to store the vaccine
After first use the mixed vaccine should not be returned to the refrigerator, but stored at less than 25 °C and used within 24 hours.
The physician should only remove from the refrigerator the vials which he or she expects to use.

PAGE TWO OF EPI-NEWS
The normal page two of EPI-NEWS including tables detailing notifications, tests/isolates and the influenza sentinel curve will not be printed this week, but it is available at www.ssi.dk (Danish language).
(Department of Epidemiology)