

Influenza vaccine and porcine gelatine

Q&As for health professionals

Why did influenza policy change in 2013/14?

This year, all healthy children aged two, three and four years, are being offered a vaccination against influenza. This follows a decision by the Joint Committee on Vaccination and Immunisation (JCVI) to introduce the vaccine for healthy children, in addition to the existing policy of vaccinating those in clinical risk groups. The policy of vaccinating all children aged 2-16 years was shown to be highly cost effective based on a mathematical modelling study reviewed by the committee.^{1 2}

Although the burden of influenza is highest in the very young and the elderly, vaccination of all children should interrupt transmission of influenza and therefore provide additional indirect or 'herd' protection to those who are most vulnerable because of their age or medical condition. Because a programme to vaccinate all 2- to 16-year-olds will be difficult to implement, however, the vaccine is being rolled out to the youngest age groups gradually, and to older children in some geographical 'pilot' areas of the UK. More children will become eligible for vaccine in future years.

Which vaccine is being used in the new programme?

The JCVI decision was based upon a programme using a live attenuated vaccine, called Fluenz[®] which is given as nasal spray. The JCVI statement said:

JCVI advises that the live attenuated intranasal influenza vaccine (Fluenz) should be the vaccine of choice for the extension to the programme, given the evidence of effectiveness, protection against drifted strains and safety, and in the absence of any equivalently effective alternative authorised vaccine. There may also be longer-term immunological advantages to the use of a live attenuated influenza vaccine.

A single dose of Fluenz provides better protection to children than inactivated influenza vaccine.^{3 4 5 6 7} There is also better evidence that Fluenz provides protection against strains that have drifted from those in the vaccine,^{8 9} and that protection is longer lasting.¹⁰

A two-dose schedule of inactivated vaccine was also considered to be more complex and challenging to implement, particularly in the school setting, and the committee considered that compliance with a full course was likely to be poor.¹¹

We have heard that Fluenz contains ingredients that come from pork – is this true?

The nasal flu vaccine does contain hydrolysed gelatine derived from pork as one of its additives. Gelatine is commonly used in a range of pharmaceutical products, including many capsules and some vaccines. The gelatine used in Fluenz is a highly purified product used to stabilise live viral vaccines.

Is it permissible for those of certain faiths to receive the vaccine?

This statement from representatives of the Jewish community may help your patients to reach a decision about having the vaccine:

Rabbi Abraham Adler from the Kashrus and Medicines Information Service, said:

It should be noted that according to Jewish laws, there is no problem with porcine or other animal derived ingredients in non-oral products. This includes vaccines, including those administered via the nose, injections, suppositories, creams and ointments.

However, we also acknowledge that some groups within the British Muslim community may consider the porcine product to be forbidden. In this circumstance, the individual would be unable to accept many pharmaceutical products unless there was no suitable alternative and/or the product was considered life-saving.

Is there an alternative live vaccine that does not contain porcine products?

There is no other live attenuated vaccine available in Europe. The product used in the UK (Fluenz) is the same product that has been used widely in the USA for over ten years, but under another name (Flumist).

Why can't the vaccine be made with another stabiliser?

As a requirement of receiving a licence from the European Medicines Agency (EMA), vaccines are stringently tested to ensure that they are safe and effective. In the development of this vaccine formulation, the manufacturer tested 40 potential stabilisers and hydrolysed gelatine was chosen – without the gelatine the stability of the formulation was significantly reduced.

Any change to the vaccine formulation would require clinical studies to show that the immune response was not inferior and would require a further assessment by the EMA. Therefore, it may take several years to produce a product with an alternative stabiliser.

Can inactivated flu vaccine be offered as an alternative?

The view of Public Health England (PHE) and the Department of Health is that, for the universal vaccination of healthy individuals, there is no suitable alternative to Fluenz. The principle of the programme is to interrupt transmission of influenza and therefore indirectly protect the whole population – including the elderly, adults and children in clinical risk groups. This is best achieved by offering Fluenz to healthy children in the age groups that contribute most to transmission – those aged 2 to 16 years.

Does this policy discriminate against people who refuse the vaccine on religious grounds?

The childhood influenza programme will help to protect everyone, vaccinated and unvaccinated, by reducing the spread of influenza in the community. Unlike the programme for those in clinical risk groups, the universal programme does not aim to provide direct protection to each individual child. For example, healthy children aged under two years, in whom Fluenz is not licensed, and who are at highest risk from influenza, are not being offered inactivated vaccine – these infants will only be protected by reducing the risk of exposure from older children. Those healthy children who are eligible for Fluenz but choose not to receive it are at lower absolute risk from influenza than these younger children.

Children in clinical risk groups, however, who do not receive Fluenz, should receive the injectable inactivated vaccine (normally with two doses), in the same way as they would under the previous programme.

Is influenza a serious disease?

Influenza is a life-threatening disease and contributes to many deaths each year, particularly the elderly and those in clinical risk groups. In addition, even in healthy people, influenza can be extremely debilitating and commonly leads to hospital admission, particularly in young infants. At best, the illness may lead to time off work for the patient or for their parent or carer.

What does PHE recommend?

PHE strongly recommends that anyone whose child is offered immunisation accepts the Fluenz vaccine to give their child the best protection against the influenza virus. This large programme has the potential to protect children against the severe complications of flu and to reduce spread to more vulnerable people such as young infants, pregnant women, and those with underlying medical conditions.

References

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