The national childhood flu immunisation programme 2014/15

Information for healthcare practitioners
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The national childhood flu immunisation programme 2014/15

Background

Following a recommendation in 2012 by the Joint Committee on Vaccination and Immunisation (JCVI) that the annual influenza vaccination programme should be extended to include all children aged two to under 17 years of age, the phased introduction of this extension began in 2013. In 2013, flu vaccine was offered to all two and three year old children, and those aged four to 10 years (up to and including pupils in school year 6) in seven different geographical pilot areas.

From 1st September 2014, the second phase of the childhood seasonal influenza (flu) vaccination programme will begin. For the 2014/15 flu season, flu vaccine will be offered to all four year old children as well as to all two and three year old children. The seven geographical pilots of primary school aged children started in 2013/14 will continue and there will also be several different geographical pilots in secondary school aged children in Years 7 and 8.

Why vaccinate children?

Extending the current flu vaccination programme to all children aims to lower the public health impact of flu by:

- protecting children and thus averting a large number of cases of flu in children
- reducing flu transmission in children thus protecting older adults and those with clinical risk factors and averting many cases of severe disease and flu-related deaths

Studies commissioned by JCVI\(^1\) suggested that, despite the high cost, extending the flu vaccination programme to all children is highly likely to be cost effective and well below the established cost effectiveness threshold when indirect protection to the whole population is taken into account, particularly over the longer term.

The cost effectiveness study also suggested that extending flu vaccination to children remained cost effective in circumstances where vaccine uptake by clinical risk groups was substantially increased.

The role of healthcare professionals

Healthcare professionals have a key role in promoting increased uptake of flu vaccination in children through:

- understanding the benefits and evidence base relating to the use of the vaccine against flu
- promoting the use of vaccine to parents/carers of children who are eligible to receive the flu vaccination
- safely administering flu vaccines, including Fluenz Tetra\(^{®}\), in accordance with the vaccine schedule
- ensuring any adverse effects are managed and reported appropriately

What is flu?
Flu is a highly infectious, acute, viral infection of the respiratory tract. It is transmitted by the inhalation of infected droplets and aerosols and by hand-to-mouth/eye contamination from an infected surface. The incubation period can be 1–5 days (average 2–3 days).

There are three types of influenza virus. Influenza A causes epidemics and pandemics. This virus is found in many different animals and may spread between them. Birds, particularly wildfowl, are the main animal reservoir. Influenza B is found predominantly found in humans and may cause epidemics. Influenza C causes minor respiratory illness only.

Who does it affect?
Flu can affect anyone, but it is a more serious illness in babies, pregnant women, older people and those with certain underlying conditions.

What are the features of flu?
In healthy individuals, flu is usually an unpleasant but self-limiting illness with recovery in five to seven days. Common symptoms include the sudden onset of fever, chills, headache, myalgia (muscle aches) & severe fatigue. Sufferers can also experience a dry cough, sore throat and stuffy nose. In young children, gastrointestinal symptoms such as vomiting and diarrhoea may be seen.

Possible complications of flu
Common complications may include bronchitis, otitis media/middle ear infection (especially in children) and sinusitis. Other less common complications include secondary bacterial pneumonia, viral pneumonia, meningitis and encephalitis.
Extended flu vaccination programme to children

Two main types of vaccine will be used: a live nasal vaccine and an inactivated intramuscular vaccine.

In the UK, the flu vaccine being used for most children in the target groups is Fluenz Tetra®, a live intranasal vaccine. It is attenuated (weakened) so that it will not cause disease but will protect against flu.

Fluenz Tetra® is marketed by Astra Zeneca and is licensed from age 24 months to less than 18 years of age. As Fluenz Tetra® is a live vaccine, not all children are able to receive it. This is covered later in this resource (see Contraindications section). Where Fluenz Tetra® is contraindicated, children should be offered inactivated flu vaccine. You should check the locally agreed arrangements for these children.

Who is the Fluenz Tetra® vaccine recommended for?

In England, all children aged 2, 3 and 4 years (but not 5 years or older) on the 1 September 2014 (ie children whose date of birth is on or after 2 September 2009 and on or before 1 September 2012) will be offered the live attenuated influenza vaccine Fluenz Tetra®. Additionally, the Fluenz Tetra® vaccine should be offered to children aged between 2 and 18 years in clinical risk groups, unless unsuitable (please refer to contraindications section below). For further information about the childhood flu immunisation programme 2014/15, please refer to ‘The national flu immunisation programme 2014/15’.

What are the potential side effects of Fluenz Tetra®?

Fluenz Tetra® has a similar adverse reaction profile to inactivated flu vaccines. Nasal congestion/runny nose (rhinorrhoea), reduced appetite, weakness and headache are common adverse reactions following administration of the live attenuated intranasal vaccine Fluenz Tetra®. Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur.

What are the contraindications to Fluenz Tetra®?

There are very few individuals who cannot receive any flu vaccine. When there is doubt, appropriate advice should be sought promptly from the screening and immunisation team in the NHS England area team, a consultant in communicable disease control or a consultant paediatrician, to minimise the period the individual is left unvaccinated. Fluenz Tetra® should not be given to a person who:

- is under 24 months or 18 years or older
- has had a confirmed anaphylactic reaction to a previous dose of flu vaccine
- has had a confirmed anaphylactic reaction to any component of the vaccine

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is allergic to eggs
- is clinically severely immunodeficient owing to the use of high-dose corticosteroids or immunosuppressive therapy for conditions such as: acute and chronic leukaemia; lymphoma; HIV infection not controlled by highly active antiretroviral therapy (HAART); cellular immune deficiencies
- has a history of active wheezing at the time of vaccination (until at least 7 days after wheezing has stopped)
- is currently taking or has been prescribed oral steroids in the last 14 days
- is currently taking a high dose inhaled steroid - Budesonide >800 mcg/day or equivalent* (e.g. Fluticasone >500 mcgs/day)
- is receiving salicylate therapy
- is pregnant

The Green Book[^3] chapter on ‘contraindications and special considerations’ (chapter 6) gives further advice on the use of live vaccines in individuals who are severely immunosuppressed. In cases of contraindication such as severe immunosuppression, severe asthma or active wheezing at time of immunisation, pregnancy or salicylate therapy, consideration should be given to the use of inactivated (that is injectable) flu vaccine.


Why is Fluenz Tetra® the vaccine of choice for most children aged two years and older?
The live attenuated influenza vaccine, Fluenz Tetra®, has been shown to provide greater and longer protection for children than inactivated influenza vaccines. In studies comparing the effectiveness of Fluenz and inactivated influenza vaccines, there were between one third and one half fewer influenza infections in groups of children given Fluenz compared with those given inactivated influenza vaccines[^4]. JCVI considers, and the Green Book recommends, that the live attenuated flu vaccine Fluenz is the preferred vaccine for children eligible to receive influenza vaccine. The 2014/15 flu season is the first season in which Fluenz Tetra® will be used. This vaccine is the same as the Fluenz® vaccine used in the UK in the 2013/14 season and used in the US for many years but with the addition of the other B virus type. The majority of published literature is about Fluenz®; most of this will apply to Fluenz Tetra® as well.

The virus within the Fluenz Tetra® vaccine is cold adapted - what does this mean?
A cold adapted virus is designed not to reproduce well at body temperature (37°C) so it will not replicate in the lungs but will reproduce at the cooler temperatures found in the nose (nasal mucosa). This allows the child to produce antibodies which then protect against infection. These antibodies work in the lining of the airways and are not produced in response to the inactivated flu vaccine. By limiting viral reproduction to the nose, the worst symptoms of flu are avoided.

Is Fluenz Tetra® effective?
Fluenz Tetra® provides greater protection for children than inactivated flu vaccine. By using a live attenuated vaccine more elements of the immune system are involved including the production of IgA, a T-cell response and cell mediated immunity.

Early results from the 2013/14 child flu vaccine pilot programme suggest a positive impact on levels of flu in primary school-aged children and that there has been both a direct and indirect impact on influenza indicators\(^5\). In pilot areas compared to non-pilot areas, there were fewer GP consultations and A&E attendances for ‘influenza like’ and respiratory illness, and fewer people tested positive for flu in primary care.

Is Fluenz Tetra® safe?
A live attenuated flu vaccine (FluMist) has been used in the USA for many years. Millions of doses have been given and it has a good safety profile in children aged two years and older. Even though it is an attenuated (weakened) live vaccine it cannot cause disease. In the 2013/14 flu season, no significant adverse reactions were reported following vaccination with Fluenz in the UK.

How should Fluenz Tetra® be stored?
Fluenz Tetra® must be stored in accordance with manufacturer’s instructions. The cold chain must be maintained. Store between +2°C and +8°C in original packaging. Do not freeze and protect from light. Fluenz Tetra® may be left out of the refrigerator for a maximum period of 12 hours at a temperature not above 25°C as indicated in the summary of product characteristics\(^6\) (SPC). If the vaccine has not been used after this 12 hour period, it should be discarded.

What is the shelf life of Fluenz Tetra®?
Fluenz has an expiry date 18 weeks after manufacture – this is much shorter than inactivated influenza vaccines. Expiry dates should be checked regularly. It is highly likely that all the Fluenz Tetra® supplied centrally will have expired by February 2015. It is therefore important to ensure that efforts are made to vaccinate children before the Christmas holidays.

How should Fluenz Tetra® be ordered?
PHE has centrally procured both live and inactivated flu vaccine for all children aged from 6 months to less than 18 years old. This is for those children who are part of the extension of the programme (2, 3 and 4 yrs and pilots) and those children in clinical risk groups who are not part of the extension (that is, PHE will supply LAIV (Fluenz Tetra®) for those who can receive it and inactivated flu vaccine for those children for whom Fluenz Tetra® is not suitable or contraindicated.

All flu vaccines for children can be ordered through the ImmForm website, as for other centrally purchased vaccines.

How is Fluenz Tetra® presented?
Fluenz Tetra® is supplied as a box containing 10 single-use, prefilled nasal applicators. Each applicator contains 0.2ml nasal suspension. The nasal applicator is ready to use. No reconstitution or dilution is required. The nasal suspension is colourless to pale yellow, clear to opalescent. Small white particles may be present.

How many doses are required?
Children NOT in clinical risk groups only require one dose of this vaccine. A single dose of Fluenz is 0.2ml (administered as 0.1ml per nostril).

The marketing authorisation holder’s Summary of Product Characteristics (SPC) states that, for children who have not previously been vaccinated against seasonal influenza, a second dose should be given after an interval of at least four weeks. The JCVI have considered this issue and have recommended that children who are not in a clinical risk group should only have a single dose of Fluenz.

Healthcare professionals are reminded that in some circumstances, the recommendations regarding vaccines given in the Green Book chapters may differ from those in the SPC for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and this advice should be followed. The Green Book recommendations and/or further advice from the Department of Health should be reflected in PGDs.

Children aged two years to less than nine years who are in a clinical risk group and who have not received influenza vaccine before should receive two doses of Fluenz. The second dose should be given at least four weeks after the first.

How is the vaccine given?
Fluenz Tetra® is administered by the intranasal route and is supplied in an applicator that allows 0.1ml to be administered into each nostril (total dose of 0.2ml in both nostrils).

What happens if the child sneezes, blows their nose or has nasal dripping following administration?
Administration of either dose does not need to be repeated. Reassurance should be given that the vaccine will still be effective if any of these occur.

What happens if half of the vaccine dose cannot be given eg because it is accidentally squirted into the child’s eye?
The vaccine may cause some slight irritation to the eye and eyewash normal saline should be used to wash out the eye. They should be advised to seek medical advice if any irritation occurs and persists beyond what might reasonably be expected.

If some of the vaccine is squirted into the child’s eye, it may cause slight irritation. The eye should be washed out with eyewash or normal saline. If any irritation occurs and persists beyond what might reasonably be expected, the parent should be advised to seek medical advice.

Does Fluenz Tetra® contain latex?
The Fluenz Tetra® vaccine is supplied in a single use nasal applicator (type 1 glass) with nozzle (polypropylene with polyethylene transfer valve), nozzle tip-protector (synthetic rubber), plunger rod, plunger stopper (butyl rubber) and dose divider clip, none of which should affect latex sensitive individuals.

Does Fluenz Tetra® contain any preservatives such as thiomersal?
No – Fluenz does not contain any preservatives, such as thiomersal.

We have heard that Fluenz Tetra® 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 Tetra 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 Tetra) is the same product that has been used widely in the USA for over ten years, but under another name (Flumist). Public Health England’s statement on influenza vaccines and porcine gelatine can be found here. The children’s flu vaccination programme, the nasal flu vaccine Fluenz and porcine gelatine Q&A document can also be found here.

What should be given to patients with egg allergy? There are no data on the use of Fluenz Tetra® in children with egg allergy. Fluenz Tetra® should not be given to those with egg allergy. For those with egg allergy who do not experience anaphylaxis, there are inactivated flu vaccines which contain low levels of egg protein that may be considered. More detail on this is provided in the Green Book Influenza Chapter 19. Vaccines with ovalbumin content more than 0.12 µg/ml (equivalent to 0.06 µg for 0.5 ml dose) or where content is not stated should not be used in egg-allergic individuals.

Can Fluenz Tetra® be administered at the same time as, or at any interval before/after other vaccines? Fluenz Tetra® can be given at the same time as, or at any interval before or after other vaccines, including live vaccines. Although it was previously recommended that, where vaccines cannot be administered simultaneously, a four-week interval should be observed between live viral vaccines, JCVI have now advised that no specific intervals need to be observed between the live attenuated intranasal influenza vaccine and other live vaccines.

Can Fluenz Tetra® be administered with antiviral agents against flu? There is a potential for flu antiviral agents to lower the effectiveness of Fluenz Tetra®. Therefore, influenza antiviral agents and Fluenz Tetra® should not be administered concomitantly. Fluenz Tetra® should be delayed for at least 48 hours after cessation of treatment with flu antiviral agents. Administration of flu antiviral agents within two weeks of administration of Fluenz Tetra® may adversely affect the effectiveness of the vaccine.

Fluenz Tetra® is not contraindicated for use in children or adolescents with stable HIV infection receiving antiretroviral therapy; those receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids; or those receiving corticosteroids as replacement therapy, for example for adrenal insufficiency.


Can Fluenz Tetra® be given when the patient has a blocked or runny nose?
There are no data on the effectiveness of Fluenz Tetra® when given to children with a heavily blocked or runny nose (rhinitis) attributable to infection or allergy. As heavy nasal congestion might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration until resolution of the nasal congestion should be considered or use of an appropriate alternative intramuscularly administered flu vaccine should be considered.

Can Fluenz Tetra® be given in pregnancy?
There are limited data from the use of live attenuated flu vaccine in pregnancy (Fluenz Tetra®). Whilst there is no evidence of risk with live attenuated influenza vaccine, inactivated influenza vaccines are preferred for those who are pregnant. There is no need, however, to specifically test eligible girls for pregnancy or to advise avoidance of pregnancy in those who have been recently vaccinated. There are no specific precautions regarding pregnant women who are exposed to children who have been vaccinated with Fluenz Tetra® as the likelihood of onward transmission is considered very low.

What if the child is unwell on the day of vaccination?
If the child has an acute severe febrile illness, Fluenz Tetra® administration should be deferred until recovered. Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination.

As Fluenz Tetra® is a live vaccine, can the vaccine virus be passed on to others?
There is the theoretical potential for transmission of the live attenuated flu virus in Fluenz Tetra® to very severely immunosuppressed contacts (for example bone marrow transplant patients requiring isolation). This risk is for the period of one to two weeks following vaccination. In the US, where there has been extensive use of the live attenuated influenza vaccine, there have been no reported instances of illness or infections from the vaccine virus among immunocompromised patients inadvertently exposed. Where close contact with very severely immunosuppressed contacts (for example household members) is likely or unavoidable, however, consideration should be given to using an appropriate inactivated flu vaccine.

Can healthcare staff in clinical risk groups administer the vaccine?
In theory, healthcare workers may have low level exposure to live attenuated influenza vaccine viruses during administration of the vaccine and/or from recently vaccinated patients. The vaccine viruses are cold-adapted and attenuated however and are unlikely to cause symptomatic influenza. In the US, where there has been extensive use of the live attenuated influenza vaccine, no transmission of vaccine virus in healthcare settings has ever been reported and there have been no reported instances of illness or infections from the vaccine virus among healthcare professionals inadvertently exposed. Thus, the Centers for Disease Control and Prevention has considered that the risk of acquiring vaccine viruses from the environment is unknown but is probably low. As a precaution, however, very severely immunosuppressed individuals should not administer live attenuated influenza vaccine. Other

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healthcare workers who have less severe immunosuppression or are pregnant, should take reasonable precautions to avoid inhaling the vaccine and ensure that they themselves are appropriately vaccinated.

**What should you do if you inadvertently administer Fluenz Tetra® to a child who is immunosuppressed?**

If an immunosuppressed individual receives live attenuated intranasal vaccine (LAIV) then they should be advised to seek medical advice if they develop flu like symptoms in the four days (the usual incubation period) after administration of the vaccine. If the patient is severely immunosuppressed, antiviral treatment should be considered in addition to the above advice. If antivirals are used, then in order to maximise their protection in the forthcoming flu season, the patient should be offered inactivated flu vaccine. This can be given straight away.

Healthcare professionals should report the administration error via their local governance system(s) so that the appropriate action can be taken, lessons can be learned and the risk of future errors minimised.

**What should you do if you inadvertently administer Fluenz Tetra® to a child who is aged less than 24 months?**

Fluenz Tetra® vaccine is contraindicated in all children aged less than 24 months due to an increase in adverse events in this age group. An increase in wheezing and hospitalisation was observed in Fluenz clinical trials that included children aged from six to 23 months of age. The decision not to license the vaccine for use in children aged less than 24 months was based on these observations rather than vaccine efficacy in this age group.

Children who have received Fluenz Tetra® vaccine at less than 24 months of age do not require additional doses. The inadvertently administered vaccine should count as a valid dose. However, the child should be carefully monitored due to the increased risk of adverse events.

Children from six months of age in clinical risk groups and who have not received an influenza vaccine previously should count the inadvertent administration of Fluenz Tetra® as the first dose. The child should also be offered the inactivated trivalent influenza vaccine four weeks later to complete the two dose schedule (in line with the recommendation that children aged six months to under 9 years who have not received inactivated influenza vaccine previously should be offered a second dose at least four weeks after the first dose).

Healthcare professionals should report the administration error via their local governance system(s) so that lessons can be learnt and the risk of future errors minimised.

**What should you do if you inadvertently administer an expired dose of Fluenz Tetra® to a child?**

Inadvertently administering an expired dose of Fluenz Tetra® is unlikely to cause significant harm to the child. Health professionals should inform the parent/guardian of the error, provide reassurance where necessary and discount the expired dose. An additional dose of Fluenz Tetra® that is in date should be offered as soon as possible to ensure satisfactory protection. In the event that ‘in date’ Fluenz Tetra® is not available, a suitable inactivated influenza vaccine should be offered as an alternative.
Inadvertently administering an expired dose of Fluenz Tetra® is a clinical incident that should be reported via the local governance system(s), so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

Which flu vaccine should be offered to a partially immunised child when all Fluenz Tetra® vaccine has expired?
In the event that eligible children (those in clinical risk groups who have never received influenza vaccine before and are aged between two and less than nine years) who have previously received one dose of Fluenz Tetra® require a second dose but all Fluenz Tetra® stock has expired, a suitable inactivated influenza vaccine should be offered as an alternative, allowing a four week minimum interval period between the two doses. It is recommended that children aged 2 to less than 3 years should receive an inactivated trivalent influenza vaccine, whilst children aged three to less than nine years should receive the recommended quadrivalent inactivated influenza vaccine (or trivalent if not possible to obtain quadrivalent).

How can the practice/school nurse recognise if someone is severely immunosuppressed?
An individual may be considered severely immunosuppressed if they fall into the following categories:

- severely immunodeficient due to conditions or immunosuppressive therapy:
- acute and chronic leukaemias
- lymphoma
- HIV positive patient not on highly active antiretroviral therapy
- cellular immune deficiencies
- high dose steroids

What should be done if an individual experiences a side effect?
As with all vaccines and other medicines, healthcare professionals and patients are encouraged to report suspected adverse reactions using the yellow card reporting scheme at http://mhra.gov.uk/yellowcard. If the vaccine is being given as part of a pilot this should be noted on the yellow card.

Can anaphylaxis occur following administration of Fluenz Tetra®?
As with all vaccines, there is a very rare possibility of this vaccine causing a severe allergic reaction (anaphylaxis). All health care professionals responsible for vaccination should be trained to recognise and treat anaphylaxis.

The use of inactivated flu vaccine
Where Fluenz Tetra® is contraindicated; children may be offered inactivated flu vaccine. Inactivated flu vaccines suitable for children are presented as prefilled syringes for intramuscular injection. The preferred site for injection is the anterolateral aspect of the thigh for infants under one year. Children over one year of age can receive the vaccine in the deltoid region of the upper arm.
Some inactivated flu vaccines are restricted to use in particular age groups or are not suitable for those with an egg allergy. Professionals must be familiar with and refer to the manufacturer’s SPC for individual brands when administering inactivated flu vaccines.

An inactivated quadrivalent vaccine (FluarixTM Tetra) is now authorised for those children aged three years and older for whom Fluenz is unsuitable. The quadrivalent vaccine has both influenza B strains and therefore may provide better protection against the circulating B strain(s) than trivalent inactivated influenza vaccines.

Inactivated flu vaccine has a similar systemic adverse reaction profile to Fluenz Tetra®. The most common adverse reactions with the inactivated flu vaccine are injection site reactions. These usually disappear after one or two days.

**How many doses of inactivated flu vaccine are required?**  
When children cannot receive Fluenz Tetra® due to a contraindication and where the child is aged six months to less than nine years and has not received flu vaccine before, they should receive two doses of inactivated flu vaccine, with the second dose at least four weeks after the first. The inactivated influenza vaccines are interchangeable – the second dose does not have to be the same vaccine given for the first dose.
Flu vaccination for winter 2014/2015

An algorithm showing this vaccination programme can be found in the latest Influenza chapter of the Green Book.

Further information can be obtained from:

Acknowledgement

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