

Influenza immunisation programme 2018/19

Factsheet for healthcare practitioners

Morbidity and mortality due to influenza can cause winter pressures within the healthcare system and major harm to individuals, particularly vulnerable people. The annual flu immunisation programme helps to reduce GP consultations, unplanned hospital admission, pressures on emergency departments and outbreaks in nursing and residential homes. It is therefore a critical element of the system-wide approach for delivering robust and resilient health and care services during the winter. Following a recommendation in 2012 by the Joint Committee on Vaccination and Immunisation (JCVI), the annual influenza programme has been extended to include children. Extending the flu vaccination programme to healthy children aims to

lower the impact of flu by providing direct protection to children and indirect protection to others. This will help to prevent cases of severe flu and flu-related deaths in older adults and people with clinical risk factors. This year, following JCVI recommendation in 2017, an adjuvanted inactivated vaccine will be used for those over 65 years of age. This vaccine aims to provide better protection for elderly. Vulnerable patients are also protected by the vaccination of health and social care workers. Uptake of flu vaccination in health and social care workers in Northern Ireland has been low and the Chief Medical Officer has highlighted the importance of increasing uptake rates among health and social care workers.

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 is one to five days (average two to three days).

There are three different 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. The influenza A virus can live and multiply in wildfowl from where it can transmit to humans.
- Influenza B tends to cause less severe disease and smaller outbreaks. It is predominantly found in humans and the burden of disease is mostly in children.
- Influenza C causes minor respiratory illness only.

Who is affected by flu?

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

What are the symptoms 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) and 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 bronchiolitis, otitis media (middle ear infection) in children and sinusitis. Other less common complications include secondary bacterial pneumonia, viral pneumonia, meningitis and encephalitis.

Does the flu vaccine offer protection against all types of flu virus?

Flu viruses change continuously and the epidemiology of flu viruses circulating throughout the world is monitored by the World Health Organization (WHO). Each year WHO makes recommendations about the strains to be included in vaccines for the forthcoming winter. Trivalent vaccines used in Northern Ireland this year will offer protection against:

- A/Michigan/45/2015 (H1N1) pdm09-like virus;
- A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus;
- B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage).

Quadrivalent vaccines will also offer protection against:

- B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage).

What vaccines are available to use this year?

There are three different types of flu vaccines available to use in Northern Ireland this year:

Inactivated influenza vaccine. This year Sanofi Pasteur Quadrivalent Inactivated Vaccine (QIV).

Adjuvanted inactivated influenza vaccine. Flud® is the only adjuvanted Trivalent Inactivated Vaccine (aTIV).

Live attenuated intranasal vaccine (LAIV). Fluenz Tetra is the only brand currently available in Northern Ireland.

Note: Always check for contra-indications before administering a vaccine

School health delivery of flu vaccine programme

If you are delivering the flu programme in schools you will have the choice of two vaccines to use. Fluenz Tetra is the vaccine of choice for all children aged 2-17, unless the vaccine is contra-indicated. It is a quadrivalent vaccine that is administered intranasally. If Fluenz Tetra is contra-indicated in a child, (regardless of whether or not they are in a clinical risk category), then a quadrivalent vaccine called Sanofi Pasteur Quadrivalent Inactivated Vaccine should be considered. This vaccine has low ovalbumin content and can be given to children with an egg allergy that did not result in anaphylaxis requiring intensive care.

Who is responsible for vaccinating children?

The school nursing team will offer vaccination to all children P1-P7 regardless of whether or not they are in a clinical risk group. They will only visit the school once and there will be no mop-up visits. Other eligible children who are in one of the clinical risk groups but who do not attend primary school will be vaccinated in primary

care. Children who miss the vaccine in school or require a second vaccine because they are under 9, are in a clinical risk group and have not previously received a flu vaccine, will receive their vaccine in primary care.

Vaccinating someone outside of the school health delivery programme

If you are vaccinating a child outside of the school setting, Fluenz Tetra is still the vaccine of choice for children age 2-17, unless contra-indicated. If the child is not able to receive Fluenz Tetra either because they are between six months and two years old or have other contra-indications, it is likely that they will still be able to receive an inactivated vaccine. The inactivated vaccine available for use in this age-group is Sanofi Pasteur Quadrivalent Inactivated Vaccine. Sanofi Pasteur Quadrivalent Inactivated Vaccine has a low ovalbumin content and can be used on patients with an egg allergy that did not result in anaphylaxis requiring intensive care.

Egg allergy and severe egg allergy

In previous years an egg-free vaccine was available for use in adults with an egg allergy. This vaccine was called Optaflu and has not been produced this year by the manufacturer. **There is therefore no egg-free vaccine available for use in adults this year.**

Most flu vaccines are prepared from flu viruses grown in embryonated hens' eggs. The final vaccine product contains varying amounts of egg proteins (as ovalbumin).

What vaccine should I use on a patient who has an egg allergy?

If a child or adult has a severe egg allergy which has previously required intensive care you should discuss with secondary care to consider vaccination in a hospital setting. It is extremely unlikely that this will be necessary for the majority of patients.

Adults with an egg allergy that does not require referral to secondary care can have flu vaccine administered in primary care using an inactivated flu vaccine with an ovalbumin content less than 0.12µg/ml (ie Sanofi Pasteur Quadrivalent Inactivated Influenza Vaccine).

Children aged 2-17 with an egg allergy that did not require referral to intensive care should be vaccinated using Fluenz Tetra, unless contra-indicated for other reasons. This advice is based on JCVI recommendations and applies regardless of whether or not the child is in one of the clinical risk categories outlined in the 'Green Book'. If Fluenz Tetra is contra-indicated then the child should be given a suitable inactivated vaccine with an ovalbumin content less than 0.12µg/ml (ie Sanofi Pasteur Quadrivalent Inactivated Influenza Vaccine). Note: The Sanofi Pasteur quadrivalent inactivated vaccine was only available for use in the school delivery programme in previous years. This quadrivalent vaccine is now available for use in primary care and for healthcare workers in the Trust delivered programme (via Occupational health / peer vaccinators). One example of when Fluenz Tetra is contra-indicated is when a child has uncontrolled asthma. It is very important that this child is protected against flu as they are in one of the clinical at risk groups. The Green Book states that these children should receive an inactivated vaccine. Therefore if a child has uncontrolled asthma and an egg allergy that did not require intensive care, they should be offered an inactivated vaccine with an ovalbumin content less than 0.12µg/ml (ie Sanofi Pasteur quadrivalent inactivated vaccine).

What vaccine should I use if the child is living in the same house as someone who is immunocompromised?

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

Should immunocompromised children or staff be excluded from school when LAIV is being administered?

Excluding children or staff from school during the period when Fluenz Tetra is being offered is not necessary. The only exception to this would be if the person is extremely immunocompromised (for example has just had a bone marrow transplant). These people are normally advised not to attend school/work because of the more definite and higher risk of them acquiring other infections.

Is it safe for a pregnant healthcare worker to administer Fluenz Tetra?

Yes pregnant healthcare workers can administer Fluenz Tetra unless they are severely immunocompromised. If this is the case they would then be excluded from work anyway.

Can a healthcare worker be exposed to vaccine virus when administering Fluenz Tetra?

Healthcare workers administering Fluenz Tetra may, theoretically, be exposed to the vaccine if it is accidentally released outside of the child's nose. In the US, where there has been extensive use of the vaccine over many years, transmission of the vaccine virus to healthcare workers has not been reported to date. The vaccine does not create an external mist and almost all the fluid is immediately absorbed into the child's nose (this explains why visible dripping from the nose is unusual). Healthcare workers who are pregnant or immunocompromised can safely administer the vaccine unless they are severely immunocompromised. Again severely immunocompromised staff would not be at work.

The virus in Fluenz Tetra 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. By limiting viral reproduction to the nose, the more serious symptoms of flu are avoided.

How many doses of flu vaccine should be given?

One dose of vaccine should be administered regardless of whether or not the inactivated or LAIV vaccine is given **unless the patient is a child under nine years who:**

- **is in a clinical risk group; and**
- **has not received flu vaccine before.**

These children should receive two doses of flu vaccine at least four weeks apart. If the first dose is given in school, then the second dose will be given in primary care. In subsequent years they can have a single dose as their immune system will already be primed. All other adults/children should receive only one dose of flu vaccine.

Note: The summary of product characteristics (SPC) for Fluenz Tetra states that for children who have not previously been vaccinated against seasonal influenza, a second dose should be given after an interval of four weeks. The JCVI has considered this issue and has recommended that as a second dose of the vaccine provides only modest protection, children who are not in a clinical risk group should be offered a single dose of Fluenz Tetra.

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 our current expert advice from JCVI and this advice should be followed.

Which flu vaccine should be administered to all partially immunised children when Fluenz Tetra has expired?

In the event that eligible children who have previously received one dose of Fluenz Tetra require a second dose but all Fluenz Tetra has expired, a suitable inactivated vaccine should be used, keeping the minimum space of four weeks between vaccines. Sanofi Pasteur Quadrivalent Inactivated Vaccine is now licensed for use in children >6 months.

What if someone is unwell on the day of vaccination?

If someone has an acute severe febrile illness, flu vaccine administration should be deferred until they have recovered. Minor illness without fever or systemic upset is not a valid reason to postpone vaccination.

Does Fluenz Tetra contain latex?

Fluenz Tetra 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 Tetra does not contain any preservatives such as thiomersal.

Does Fluenz Tetra contain pork-derived ingredients?

Fluenz Tetra contains hydrolysed gelatin 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 gelatin used in Fluenz Tetra is a highly purified product used to stabilize live viral vaccines.

If someone refuses Fluenz Tetra on the basis of religious belief, can they be offered the inactivated vaccine?

Yes, in Northern Ireland a suitable inactivated vaccine can be offered when Fluenz Tetra has been refused on the grounds of religious belief (ie Sanofi Pasteur quadrivalent inactivated vaccine).

What is the shelf life of Fluenz Tetra?

Fluenz Tetra has a short expiry date of 18 weeks after manufacture. Expiry dates should be checked regularly and only the required amount of vaccines should be ordered. Please do not overstock. There is no shortage of Fluenz Tetra and Movianto will deliver the next working day providing the order is placed by 5pm. Please take this into account if ordering for weekend clinics and order by 5pm on Thursday at the latest.

Is Fluenz Tetra effective?

Fluenz Tetra provides good overall protection for children against influenza virus and is expected to provide some cross protection against mismatched strains. Using a live attenuated vaccine provides a better immune response. Vaccine effectiveness varies from year to year depending upon the circulating strains and the vaccine composition.

Following reports in the US of the low effectiveness of Fluenz Tetra, JCVI reviewed effectiveness data from the UK, Finland, Canada and the US. Most of the data demonstrates good overall effectiveness and JCVI continue to recommend the use of Fluenz Tetra and strongly support the continuation of the UK childhood influenza immunisation programme.

How long after administration of the flu vaccine does it take for someone to acquire protective immunity levels?

The flu vaccine should be administered as early in the season as possible as it takes approximately two weeks for the body to acquire protection following immunisation.

What happens if a child sneezes / develops a nasal drip / blows their nose following administration of Fluenz Tetra?

Administration of the vaccine does not need to be repeated. Binding of the virus vaccine to the epithelial cells occurs very rapidly and there are more virus particles in the vaccine than are needed to establish immunity. Reassurance should be provided that vaccine does not need to be given again.

What should happen if a child with heavy nasal congestion attends for vaccination?

The child can be offered a suitable inactivated vaccine (ie Sanofi Pasteur Quadrivalent Inactivated Vaccine) if they have heavy nasal congestion that cannot be temporarily cleared by blowing their nose.

What should happen if only half of the Fluenz Tetra vaccine is administered (because the child refuses or moves away when vaccine is being administered)?

It is not necessary to repeat the vaccine as long as 0.1 ml (half dose) has been given.

Can Fluenz Tetra be administered to a child under two years old?

No. The vaccine is not licensed for use in children under two years old.

What should you do if Fluenz Tetra is inadvertently administered to a child under two years?

Fluenz Tetra is contra-indicated in all children under two years old due to an increase in adverse events in this age group. It is not licensed for use in children under two years old for this reason. Children under two who receive Fluenz Tetra do not require a replacement dose but the parents should be informed of possible adverse events in the short term and advised to seek medical advice if these occur. They should be reassured that no long-term effects from receiving Fluenz Tetra are anticipated. If the child is under two, is in one of the clinical risk groups and never previously received a flu vaccine, they should be offered an appropriate inactivated flu vaccine four weeks later.

Note: 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 Fluenz Tetra is inadvertently administered to a child who is immunosuppressed?

If an immunosuppressed child receives Fluenz Tetra then the degree of immunosuppression should be assessed. If the individual is severely immunocompromised, antiviral prophylaxis should be considered, otherwise they should be advised to seek medical advice if they develop flu-like symptoms in the four days (the usual incubation period) following administration of the vaccine. If antivirals are used for

prophylaxis or treatment, then in order to maximise their protection in the forthcoming flu season, the patient should also be offered inactivated influenza vaccine. This can be given straight away.

Note: 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.

An individual can be considered severely immunosuppressed if they:

- are severely immunodeficient due to conditions or immunosuppressive therapy;
- have acute/chronic leukaemia;
- have lymphoma;
- are HIV positive and are not on highly active antiretroviral therapy;
- have a cellular immune deficiency;
- are taking a high dose of steroids.

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 has now advised that no specific intervals need to be observed between the live attenuated intranasal flu vaccine and other live vaccines. See <https://www.gov.uk/government/publications/revise-recommendations-for-administering-more-than-1-live-vaccine>

What should you do if you inadvertently administer an expired dose of Fluenz Tetra?

Inadvertently administering an expired dose of Fluenz Tetra is unlikely to cause harm to the child, other than that the expired dose may not offer them adequate protection. Health professionals should inform the patient/carer 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 (on the same day as the expired vaccine was given or as soon as the error was

discovered), to ensure satisfactory protection. There is no minimum interval between an expired and a valid dose of Fluenz Tetra as it is the same product being administered. In the event that in date Fluenz Tetra is not available, a suitable inactivated flu vaccine should be administered as an alternative as soon as possible.

Note: Inadvertently administering an expired dose of Fluenz Tetra is an adverse 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.

Can Fluenz Tetra vaccine be administered with antiviral agents against flu?

There is a potential for flu antiviral agents to lower the effectiveness of Fluenz Tetra vaccine. If anti-virals have been given it is better to wait until 48 hours after completing anti-virals before administering Fluenz Tetra.

Why is it important to encourage pregnant women to get their flu vaccination?

There is good evidence that pregnant women are at increased risk from complications if they contract flu. In addition there is evidence that having flu during pregnancy may be associated with premature birth and smaller birth size and weight and the flu vaccine may reduce the likelihood of this happening. Influenza vaccination during pregnancy provides passive immunity against flu to infants in the first few months of life.

Can the flu vaccine be given at any stage during pregnancy?

Yes. A review of studies on the safety of flu vaccine in pregnancy concluded that inactivated flu vaccine can be safely and effectively administered during any trimester of pregnancy. No study to date has demonstrated an increased risk of either maternal complications or adverse fetal outcomes associated with inactivated influenza vaccine. The flu vaccine should be given for every pregnancy as the flu virus changes from one season to another.

What Flu vaccine should be given to adults aged between 18 and 64 years old?

The vaccine recommended for adults age between 18 and 64 years this year in Northern Ireland is Sanofi Pasteur quadrivalent inactivated vaccine, unless it is contra-indicated.

What Flu vaccine should be given to Adults aged 65 and older?

Adults age 65 and older should receive Flud® aTIV contains an oil-based adjuvant called MF59C and as recommended by JCVI in June 2017, unless contra-indicated. The immune response to inactivated flu vaccines has been shown to decline with age. Adjuvants are added to vaccines to make the response better. Flud® Adjuvanted Trivalent Inactivated Vaccine is more effective in older people, especially those 75 and older, compared to non-adjuvanted inactivated vaccines.

If a patient aged 65 and over inadvertently receives Sanofi Pasteur quadrivalent inactivated vaccine should they be revaccinated with Flud® adjuvanted Trivalent Inactivated Vaccine?

No the patient does not need to be revaccinated. Flud® adjuvanted Trivalent Inactivated Vaccine is the vaccine recommended in those 65 years and over but Sanofi Pasteur quadrivalent inactivated vaccine is also licensed in this age group and should offer protection against flu. For this reason and also because the safety and effectiveness of administering Flud® adjuvanted Trivalent Inactivated Vaccine shortly after Sanofi Pasteur quadrivalent inactivated vaccine has not been established, no further vaccination is recommended this flu season for an individual who has inadvertently received QIV. The patient should be offered reassurance and the incident should be reported via local arrangements to prevent this from happening again.

If a patient < 65 years of age in an at-risk category inadvertently receives Flud® adjuvanted Trivalent Inactivated Vaccine what should happen?

Although a Flud® adjuvanted Trivalent Inactivated Vaccine is not licensed for those < 65 years of age in the UK, the vaccine should still provide protection to those less than 65 years who receive it inadvertently. No further vaccination is required this flu season. The patient should be offered reassurance and advised of the risk of local reactions. The incident should be reported via local arrangements to prevent this from happening again.

If a patient attends for vaccination before their 65th birthday can they be offered Flud® adjuvanted Trivalent Inactivated Vaccine?

No, the vaccine is only licensed for use from 65 years+ and patients attending for vaccination before their 65th birthday should be offered Sanofi Pasteur quadrivalent inactivated vaccine, if it is not contra-indicated.

What route of administration should be used to administer the inactivated vaccines?

The inactivated influenza vaccine should be administered as an intramuscular injection. For infants aged six months to one year, the anterolateral aspect of the thigh should be used. For those aged from one year and over, the deltoid is the preferred muscle.

Due to the presence of the adjuvant (MF59), Flud® aTIV **should be administered intramuscularly using a 25mm needle** to enable the vaccine to be delivered into the muscle. Flud® aTIV is being supplied with an orange hub 25mm needle. Immunisers should not confuse this with the shorter orange (16mm) needle used to give subcutaneous injections.

What route of administration should be used to administer Flud® in patients taking anticoagulants or with a bleeding disorder?

There is a lack of evidence to support the hypothesis that the subcutaneous route of vaccination is any safer than the intramuscular route in patients taking anticoagulants. The subcutaneous route of administration can be associated with an increase in localised reactions. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. They can receive Flud® using the orange 25G 1 inch needle supplied in boxes separately from the vaccine.

If the doctor of a patient with a bleeding disorder who is familiar with the individual's bleeding risk approves, Flud® can also be administered intramuscularly, using the orange 25G 1 inch needle supplied in boxes separately from the vaccine.

Note: In clinical trials the incidence of both mild local and systemic reactions following immunisation with Flud® was found to be higher than the incidence of reactions following the administration of vaccines that are not adjuvanted.

How long does it take for the flu vaccine to become effective?

Immune response following flu vaccination takes approximately two weeks to develop. It is important to get vaccinated by the end of November before flu starts circulating.

Can flu vaccines give you flu?

Fluenz Tetra could potentially cause flu in an individual who is immunocompromised which is why it is contra-indicated in this case. All other flu vaccines are inactivated and do not contain live viruses. This means that they are not able to cause flu.

What should I do if a patient reports a serious reaction to the flu vaccine?

All serious reactions following flu vaccination should be reported to the Medicines and Healthcare Products Regulatory Agency using the Yellow card scheme at <http://yellowcard.mhra.gov.uk/>

Note: Fluenz Tetra and Sanofi Pasteur quadrivalent inactivated vaccine carry a black triangle symbol and this is to encourage reporting of all suspected adverse reactions.

Where can I find information about groups who are eligible for flu vaccine?

Details of clinical risk groups and other groups can be found in annex 2 of the CMO letter.

www.health-ni.gov.uk/publications/letters-and-urgent-communications-2018

Vaccine fridge capacity

Please note that GPs should ensure that there is sufficient fridge capacity to store flu vaccines. It is very important to note that frequent delivery of vaccines can be made by Movianto and that there is no need to stockpile large quantities of vaccine.

Where can I get more information?

Seasonal Influenza (CMO letter) www.health-ni.gov.uk/publications/letters-and-urgent-communications-2018

The Green Book influenza chapter www.gov.uk/government/publications/influenza-the-green-book-chapter-19

On-line training (Includes flu) www.publichealth.hscni.net/directorate-public-health/health-protection/immunisationvaccine-preventable-diseases

www.fluawareni.info

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