Influenza immunisation programme 2024/25

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. Since 2020, we have faced the double threat of COVID-19 and influenza. Studies show that for some people with both COVID-19 and flu virus, there is an increased risk of complications and death. Each year the flu vaccine protects against the most common strains of flu likely to be circulating and it is more important than ever to be sure to get the flu vaccine this year. Most people will have had an opportunity to have a COVID-19 vaccine and an autumn booster programme will be offered for eligible groups 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 recommendations by the Joint Committee on Vaccination and Immunisation (JCVI),

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 handto-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.

the annual influenza immunisation programme continues to include all primary school children and young people up to and including Year 12 of secondary school. Extending the flu immunisation 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. Following JCVI recommendation in 2017, an adjuvanted inactivated vaccine will be used for those over 65 years of age. This vaccine provides better protection for the 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 improved in some Trusts but is still low compared to other parts of the UK and the Chief Medical Officer has again highlighted the importance of increasing uptake rates among health and social care workers.

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. It is recommended that **trivalent influenza vaccines** for use in the 2024/25 northern hemisphere influenza season contain the following:

Egg-based vaccines

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- an A/Thailand/8/2022 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)like virus.

Cell- or recombinant-based vaccines

- an A/Wisconsin/67/2022 (H1N1)pdm09-like virus;
- an A/Massachusetts/18/2022 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)like virus.

For quadrivalent egg- or cell culture-based or recombinant vaccines for use in the 2024/25 northern hemisphere influenza season, the WHO recommends inclusion of the following as the B/ Yamagata lineage component:

- a B/Phuket/3073/2013 (B/Yamagata lineage)like virus.
- Since March 2020, there have been no confirmed detections of wild type B/Yamagata lineage by the UK national influenza centre or internationally through any WHO influenza collaborating centres (as at August 2023). The public health risk from B/Yamagata is now considerably lower than at the time of the introduction of quadrivalent vaccines and B/Yamagata may be extinct. Therefore trivalent influenza vaccines, without a B/Yamagata strain, are currently considered clinically suitable.

As manufacturers start to produce trivalent products, their use will be preferred over the equivalent quadrivalent formulation.

What vaccines are available to use this year?

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

Inactivated influenza vaccine (cell grown).

Flucelvax[®] Tetra (QIVc) is a Quadrivalent Inactivated Vaccine that has been prepared in cell culture.

Adjuvanted inactivated influenza vaccine.

Fluad[®] Tetra Seqirus generic adjuvanted Quadrivalent Inactivated Vaccine (aQIV).

Live attenuated intranasal vaccine (LAIV).

Fluenz[®] 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 is the vaccine of choice for all children aged 2-17, unless the vaccine is contra-indicated. It is a trivalent vaccine that is administered intranasally. If Fluenz is contra-indicated in a child, (regardless of whether or not they are in a clinical risk category), then Flucelvax Tetra, a cell-based Quadrivalent Inactivated Vaccine (QIVc), should be considered. Both of these vaccines 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 from P1 up to and including Year 12 of secondary school, regardless of whether or not they are in a clinical risk group. If a child misses the vaccine in school, they will be given another opportunity to receive it either in school or at another venue. Other eligible children who are in one of the clinical risk groups but who do not attend primary school or up to Year 12 of secondary school will be vaccinated in primary care. If a child is absent from school/alternative venue during the prearranged date(s) or require a second vaccine (because they are in a clinical risk group and under 9 years of age and have not previously received a flu vaccine) they will be advised by the school health team to contact their GP.

Vaccinating someone outside of the school health delivery programme

If you are vaccinating a child outside of the school setting, Fluenz is still the vaccine of choice for children aged 2-17, unless contra-indicated, in which case they can be vaccinated with Flucelvax Tetra, a cell-based Quadrivalent Inactivated vaccine (QIVc). If the child is not able to receive Fluenz because they are between six months and two years old, they should receive cell-based Quadrivalent Inactivated vaccine (QIVc).

Is Quadrivalent Inactivated vaccine (QIVc) licensed for children aged under 2 years?

Quadrivalent Inactivated vaccine (QIVc) is not licensed for children under 2 years of age. However, for 2024/25 the JCVI advises use of this vaccine 'off-label' to at-risk children aged between 6 months and 2 years.

This recommendation to administer the vaccine 'off-label' is supported by unpublished data that show non inferiority immunogenicity and a very similar safety profile for QIVc compared with QIVe in children under 2 years old.

Egg allergy and egg allergy resulting in anaphylaxis requiring intensive care admission

Most flu vaccines are prepared from flu viruses grown in embryonated hens' eggs and the final products contain varying amounts of egg (as ovalbumin). Adults with an egg allergy can be immunised in any setting using a cell-based Quadrivalent Inactivated Vaccine (QIVc) because it is egg free. Seqirus generic (aQIV) should **not** be used on anyone who has any type of egg allergy.

Anyone with an egg allergy that resulted in anaphylaxis requiring an intensive care admission can be immunised with a cell-based Quadrivalent Inactivated Vaccine (QIVc) (Flucelvax Tetra). QIVc can also be used in patients who have a latex allergy.

Children with an egg allergy can be safely vaccinated with Fluenz (LAIV, in any setting, including primary care and schools, unless contra-indicated for another reason eg immunosuppression/acute/severe asthma. Fluenz should be given to **children who required admission to intensive care for previous anaphylaxis to egg but only** in a hospital setting (recommended by JCVI). The administration of Fluenz in this case is not covered by a PGD and a PSD will be required. When Fluenz is contraindicated, children can receive Flucelvax (QIVc).

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 to very severely immunosuppressed contacts (for example bone marrow transplant patients requiring isolation) for one to two weeks following vaccination. Following extensive use of LAIV in the UK (over 25 million doses), there has been no reported illness or infections from the vaccine virus amongst immunocompromised patients inadvertently exposed. However, 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 Fluenz is being administered?

Excluding children or staff from school during the period when Fluenz 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?

Yes, pregnant healthcare workers can administer Fluenz 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?

Healthcare workers administering Fluenz may, theoretically, be exposed to the vaccine if it is accidentally released outside of the child's nose. Following 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 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 in a clinical risk group and is under 9 years of age and has not received the 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 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.

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 has expired?

In the event that eligible children who have previously received one dose of Fluenz require a second dose but all Fluenz has expired, a suitable inactivated vaccine should be used, keeping the minimum space of four weeks between vaccines. Cell-based Quadrivalent Inactivated Vaccine (QIVc) is licensed for use in children over two years old.

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 contain latex?

Fluenz 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 contain any preservatives such as thiomersal?

No, Fluenz does not contain any preservatives such as thiomersal.

Does Fluenz contain pork-derived ingredients?

Fluenz 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 is a highly purified product used to stabilize live viral vaccines.

If someone refuses Fluenz 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 has been refused on the grounds of religious belief (ie cell-based Quadrivalent Inactivated Vaccine (QIVc).

What is the shelf life of Fluenz?

Fluenz has a short expiry date of 15 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 and Movianto should be able to deliver within two working days, provided orders are placed before the cut off time. Please take this into account if ordering for weekend clinics and order by 5pm on Thursday at the latest.

Is Fluenz effective?

Fluenz 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.

Data from many countries, including the UK, Finland, Canada and the USA demonstrates good overall effectiveness and JCVI continue to recommend the use of Fluenz and strongly support the continuation of the UK childhood influenza immunisation programme.

There is also evidence that LAIV may reduce the risks of secondary bacterial infections such group A streptococcus.

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

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 cell-based Quadrivalent Inactivated Vaccine (QIVc) if they have heavy nasal congestion that cannot be temporarily cleared by blowing their nose.

What should happen if only half of the Fluenz 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 be administered to a child with severe asthma or active wheezing?

JCVI have advised that, on the basis of recent data, children with asthma on inhaled corticosteroids may safely be given LAIV, irrespective of the dose prescribed.

LAIV is **not recommended** for children and adolescents currently experiencing an acute exacerbation of asthma symptoms, including those who have had increased wheezing and/or needed additional bronchodilator treatment in the previous 72 hours. Such children should be offered a suitable inactivated influenza vaccine to avoid a delay in protection.

There are limited safety data in children who require regular oral steroids for maintenance of asthma control, or have previously required intensive care for asthma exacerbation, such children should only be given LAIV on the advice of their specialist. As these children may be at higher risk from influenza infection, those who cannot receive LAIV should receive a suitable inactivated influenza vaccine ie cell-based Quadrivalent Inactivated Vaccine (QIVc)).

Children with significant asthma and aged under 9 years who have not been previously vaccinated against influenza will require a second dose (of either LAIV or inactivated vaccine as appropriate).

Can Fluenz 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 is inadvertently administered to a child under two years?

Fluenz 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 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 longterm effects from receiving Fluenz 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 is inadvertently administered to a child who is immunosuppressed?

If an immunosuppressed child receives Fluenz 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 (QiVc). 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 be administered at the same time as, or at any interval before/after other vaccines?

Fluenz 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 Chapter 6 of the Green Book.

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

Inadvertently administering an expired dose of Fluenz 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 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 as it is the same product being administered. In the event that in date Fluenz is not available, a suitable inactivated flu vaccine (QIVc) should be administered as an alternative as soon as possible.

Note: Inadvertently administering an expired dose of Fluenz 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 vaccine be administered with antiviral agents against flu?

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

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 offers protection against the serious complications of flu, including pneumonia and intensive care admission, and 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 aged between 18 and 64 years this year in Northern Ireland is a cell-based Quadrivalent Inactivated Vaccine (QIVc) (Flucelvax Tetra) unless it is contradicted.

What flu vaccine should be given to adults aged 65 and older?

Adults aged 65 and older should receive adjuvanted Quadrivalent Inactivated Vaccine (aQIV) Fluad Tetra, which contains an oil-based adjuvant called MF59C.1, 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. Adjuvanted Quadrivalent Inactivated Vaccine (aQIV) is more effective in older people, especially those 75 and older, compared to non-adjuvanted normal dose inactivated vaccines.

If a patient < 65 years of age in an atrisk category inadvertently receives adjuvanted Quadrivalent Inactivated Vaccine what should happen?

Although an adjuvanted Quadrivalent Inactivated Vaccine is not licensed for those under 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 adjuvanted Quadrivalent Inactivated Vaccine (aQIV)?

No, the vaccine is only licensed for use from 65 years+ and patients attending for vaccination before their 65th birthday should be offered Flucelvax Tetra (QIVc), 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 (MF59C.1), aQIV **should be administered intramuscularly using a 25mm needle** supplied with the vaccine.

What route of administration should be used to administer the vaccine 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-todate 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 the vaccine using the needle supplied. If in any doubt consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy.

Patients with a bleeding disorder may be vaccinated intramuscularly if in the opinion of the doctor familiar with the patient's bleeding risk, vaccines or similar intramuscular injections can be administered safely by this route.

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 if vaccine is available before flu starts circulating.

Timing of vaccination for older adults and eligible individuals aged over 18 years.

Influenza activity typically peaks in late December, January or February, and is not usually significant in the UK before the middle of November. While seasons can start early (such as in 2003 with circulation of a reassortment A(H3N2)), the potential impact of in-season waning of vaccine protection in adults (particularly older adults) needs to be considered in the timing of immunisation, so that protection is maintained through the period of peak risk. Evidence suggests better protection in the 14 to 90 days after vaccination than 91 or more days since vaccination. Therefore, the JCVI have recommended that vaccination for older adults and the majority of eligible individuals aged 18 years and over should commence in October 2024. The exceptions to this advice, are pregnant women and individuals who require earlier vaccination for a clinical indication, for example, prior to commencing a new immunosuppressive therapy.

Pregnant women are not expected to loose protection as rapidly as older adults, and offering vaccination as early as possible during the flu vaccine season will ensure the best possible protection is offered to mother and baby, including if the infant is born prematurely.

Available data does not indicate equivalent waning in children, supporting vaccination of children from the earliest availability of the vaccines in September.

Can flu vaccines give you flu?

Fluenz 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 vaccination should be reported to the Medicines and Healthcare Products Regulatory Agency using the Yellow card scheme at <u>www.mhra.gov.uk/yellowcard</u> **Note:** Fluad Tetra (aQIV) and Flucelvax Tetra (QIVc) vaccine carry a black triangle symbol and this is to encourage reporting of all suspected adverse reactions.



Details of clinical risk groups and other groups can be found in of the CMO letter. <u>https://www.health-ni.gov.uk/sites/default/files/</u>

publications/health/doh-hss-md-33-2024.pdf

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?

A range of information for healthcare professionals is available at: <u>www.pha.site/seasonal-influenza</u>

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