The national influenza immunisation programme 2019 to 2020

Inactivated influenza vaccine information for healthcare practitioners
About Public Health England

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SUSTAINABLE DEVELOPMENT GOALS
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Background

The seasonal influenza vaccination programme was introduced in England during the late 1960s to protect those in clinical risk groups. These groups were found to be at higher risk of influenza associated morbidity and mortality. Since then, the programme has been extended to include all those aged 65 years and over (2000) and pregnant women (2010).

During 2013, a phased programme commenced to offer influenza vaccine to all children from 2 years of age. During the 2019/20 flu season, this programme will be extended. Influenza vaccine will continue to be offered to children in at-risk groups but the upper age for the routine childhood programme will be extended so that flu vaccine will also be offered to all children who are aged two to ten years of age (but not eleven years or older) on 31 August 2019. These children will be offered live attenuated influenza vaccine (LAIV) unless contraindicated and in an at-risk group.


The requirements of the influenza vaccination programme are set out in the following key documents:

1. **Annual flu letter 2019/20** provides detailed information to support the successful implementation of the programme
2. **NHS public health functions agreement 2019-20 Service specification No.13 Seasonal influenza immunisation programme (2019-20 programme)** enables NHS England to commission influenza immunisation services to a standard that will prevent infections and outbreaks caused by flu viruses
3. **Enhanced service specification for the influenza and pneumococcal vaccination programmes 2019/20** describes the services to be provided by GP practices delivering the programme in England

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4. Green Book Influenza chapter\(^4\) provides information on influenza disease, epidemiology, the vaccines and the vaccination programme

Additional resources to support the implementation of the programme include template letters, leaflets, posters, a training slide set and an e-learning programme, all of which can be found on the Annual flu programme page of the GOV.UK website. Any updates to the flu programme are also published in the monthly PHE publication Vaccine Update.

The information in this document focuses on the inactivated influenza vaccine. A separate document containing information for healthcare practitioners on the childhood programme (The national childhood flu immunisation programme 2019 to 2020: information for healthcare practitioners) is also available.

**Influenza**

Influenza is a highly infectious, acute viral respiratory tract infection which has a usual incubation period of 1 to 3 days. Patients can experience sudden onset of symptoms such as dry cough, headache, fever and extreme fatigue.

There are 3 types of influenza virus which affect humans: types A, B and C. Types A and B are responsible for most disease. Influenza is spread by droplets, aerosol or through direct contact with the respiratory secretions of someone with the infection. For otherwise healthy individuals, it is usually a mild self-limiting disease with recovery occurring within 2 to 7 days.

Further information on influenza infection is included in the Green Book Influenza chapter and on NHS.UK.

**Influenza vaccination programme**

The purpose of the influenza vaccination programme is to protect those most at risk of developing severe disease or complications or from dying if they develop the infection.

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Individuals not eligible for vaccination, for example, infants under the age of six months, will benefit from passive protection if their mother received the vaccine during pregnancy.

Vaccination of eligible individuals should commence as soon as stock of the recommended vaccine is available and given in sufficient time to ensure patients are protected before flu starts circulating. However, eligible patients can be offered influenza vaccine at any point in the flu season and the enhanced service specification for flu includes payment for vaccines given up until 31 March 2020.

Risk groups and influenza vaccine eligibility

Influenza can affect anyone although those aged over 65 years, those with underlying health conditions, pregnant women and children under six months of age have a higher risk of developing severe disease or complications such as bronchitis or secondary bacterial pneumonia, or otitis media in children.

In the 2019/20 flu season, for those aged from six months to less than 65 years of age, clinicians should offer flu immunisation, based on individual assessment, to clinically vulnerable individuals such as those with:

- chronic (long-term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis
- chronic heart disease, such as heart failure
- chronic kidney disease at stage 3, 4 or 5
- chronic liver disease
- chronic neurological disease, such as Parkinson’s disease or motor neurone disease, or learning disability
- diabetes
- splenic dysfunction or asplenia
- a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)
- morbidly obese adults aged 16 years and over (defined as BMI of 40kg/m² and above)
- all pregnant women, including those who become pregnant during the delivery of the influenza programme, are eligible to receive influenza vaccine at any stage of pregnancy

Further details of all those eligible to receive the vaccine can be found in Chapter 19 of the Green Book and in the Annual flu letter for 2019/20.
Inactivated influenza vaccines recommendations

There are a number of changes in the flu vaccines that the Joint Committee on Vaccination and Immunisation (JCVI) has advised for use in the different patient groups for the 2019/20 flu season. The changes are in response to a wider range of vaccines being available which offer better protection5.

Adults 65 years of age and over

For vaccination of those aged 65 years and over, JCVI advises the use of any one of the following inactivated vaccines:

- adjuvanted trivalent influenza vaccine (aTIV)
- cell-based quadrivalent influenza vaccine (QIVc)
- high-dose trivalent influenza vaccine (TIV-HD)

These vaccines are considered equally suitable for use in those aged 65 years and over and are preferable to standard egg-based inactivated trivalent and quadrivalent vaccines (TIVe/QIVe). However, the high-dose trivalent influenza vaccine (TIV-HD) will not be commissioned by NHS England or reimbursed for use in the NHS Influenza vaccination programme in 2019/20 because it has a significantly higher list price6.

Adults (including pregnant women) aged under 65 years and children in clinical risk groups

For vaccination of adults aged less than 65 years of age, JCVI advises the use of any one of the following inactivated vaccines:

- cell-based quadrivalent influenza vaccine (QIVc)
- egg-grown quadrivalent influenza vaccine (QIVe)

These vaccines are considered equally suitable for use in those less than 65 years of age and in an at-risk group (subject to licensed age indications). These vaccines are

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5 Joint Committee on Vaccination and Immunisation. Advice on influenza vaccines for 2019/20. Published October 2018. Available at: www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#influenza-vaccines-jcvi-advice

preferable to standard egg based inactivated trivalent vaccines (TIVe).

Children aged from 2 years to less than 18 years are recommended to receive the live attenuated quadrivalent influenza vaccine (LAIV) unless contraindicated. QIVe will be centrally supplied for children in risk groups for whom LAIV is contraindicated or otherwise unsuitable. Further information on this vaccine and the childhood flu programme can be found on the PHE national flu immunisation programme page.

As LAIV is not licenced for use in those aged 6 months to 2 years, eligible at-risk children are recommended to receive an age appropriate inactivated quadrivalent influenza vaccine (injected). QIVe will be centrally supplied for these children.

**Quadrivalent influenza vaccines**

Quadrivalent influenza vaccines (QIV) contain two influenza A strains and the two main influenza B strains. By including both B strains, they should provide better protection in seasons when the circulating influenza B strain is not well matched to the single B strain contained in the previously used non-adjuvanted, standard-dose trivalent vaccines (TIV).

As influenza B is relatively more common in children than older age groups, the main clinical advantage of quadrivalent vaccines is in childhood. The use of the quadrivalent LAIV in children should not only protect the age group where flu infection is most common but additionally, by preventing transmission from children to others, it also reduces circulation of influenza B across the whole population and thus indirectly protect them.

However, modelling suggests that, even once the programme in children of primary school age is fully established, there is still benefit from using QIV in adults under 65 years of age in clinical risk groups, including pregnant women. Healthcare workers are also likely to benefit from protection against the additional B strain. For the 2019/20 flu season, a quadrivalent cell-based vaccine is also one of the vaccines recommended for 65 years and over age group.

Quadrivalent flu vaccines may be either egg-grown or cell-based.

**Egg-grown quadrivalent influenza vaccine (QIVe)**

In 2018/19, for those aged under 65 years, the **egg-grown quadrivalent influenza vaccine (QIVe)** was recommended as this vaccine protects against four strains of flu, providing better protection against the circulating flu B strain(s) more likely to affect this younger patient group compared to older people. Egg-grown flu vaccines are available and are again recommended for those aged under 65 years in the 2019/20 flu season.
Cell-based quadrivalent influenza vaccine (QIVc)

For the 2019/20 flu season, a cell-based quadrivalent influenza vaccine (QIVc) is available. Virtually all previous flu vaccines have been cultured in fertilised chicken eggs but when flu vaccine viruses are grown this way, the viruses adapt to live in the egg. This can lead to changes in the viruses during the manufacturing process which means the egg-derived virus used in the vaccine is then not a complete antigenic match to the original wild-type strain recommended by the WHO. This means the vaccine virus may not match the circulating flu strain as closely and the vaccines produced may therefore not be as effective. Although this ‘egg adaptation’ has been known about for a long time, it has become more of a problem in the last decade, particularly for the A(H3N2) virus which appears to be more affected by egg adaptation than the other flu A and B viruses.

The cell-based vaccine manufacturing process uses animal cells to grow the influenza virus. The original cells used in the cell line in which the influenza vaccine viruses are grown were taken by Madin and Darby from the kidney tubule of an adult dog in 1958 and this is known as the Madin-Darby Canine Kidney (MDCK) cell line. This is the cell line that is still used today so the cell-based manufacturing process does not require any new cells to be taken. The MDCK cell line is used because the influenza virus grows well in it, it is able to produce high volumes of flu virus for use in vaccines and the influenza virus isolated following culture in these cells retains the antigenic properties of the original strain. So this method of vaccine virus production should result in the vaccine virus being a closer match to the wild-type circulating flu viruses (although theoretically cell-adaptation can still occur). After the vaccine viruses are grown, they are highly purified and this purification process removes the cell culture materials which means that it is unlikely that any cell culture material remains in the vaccine.

Cell-based flu vaccines have been approved for use in the US and in multiple European countries and cell culture methods are used to grow viruses used in other vaccines (such as rotavirus, polio, rubella, shingles, chickenpox).

Further information on cell-based flu vaccines is available at: www.cdc.gov/flu/prevent/cell-based.htm

Trivalent influenza vaccines

Standard-dose trivalent influenza vaccines are not recommended to be used in any age or clinical risk group for the 2019/20 influenza season.

In response to increasing evidence of the limited effectiveness of non-adjuvanted, standard-dose egg-based influenza vaccines in older people, some pharmaceutical
companies have developed vaccines that lead to a better immune response in this group: adjuvanted and high-dose vaccines.

The trivalent vaccines that are recommended for use by JCVI are the adjuvanted and the high-dose influenza vaccines. These are described below:

**Adjuvanted influenza vaccines**

An adjuvanted trivalent inactivated influenza vaccine (aTIV), Fluad, was licensed for use in those aged 65 years and older in the UK in 2017 and widely used in the 2018/19 flu season. The aTIV has been licensed in some countries in Europe since 1997 and in the USA since 2015. It has been used for 20 years, is now used in over 20 countries and over 93 million doses have been distributed.

Published data indicates that aTIV has higher immunogenicity and effectiveness than non-adjuvanted vaccines in older people. Modelling indicates that aTIV would be highly cost-effective in both the 65-74 and 75 year and over age groups with large reductions in GP consultations and hospitalisations.

Adjuvanted vaccines are vaccines which have had a very small amount of a substance (for example, an aluminium salt) added to them to help create a stronger immune response to that vaccine. More information can be found in the section on Influenza vaccine components below.

At the present time, there are no adjuvanted quadrivalent vaccines licensed in the UK. Based on the existing evidence, JCVI have said that the adjuvanted vaccine should be offered to 65 year olds and over, even though it is trivalent. Although quadrivalent vaccine offers the potential to provide broader direct protection against influenza B, this strain is relatively less common in the elderly than in children and young adults. The successful childhood programme which uses quadrivalent LAIV is likely to offer indirect protection by reducing transmission of the additional B strain contained in the quadrivalent vaccine.

**High-dose influenza vaccines**

A high dose trivalent influenza vaccine (TIV-HD) was licensed for use in the UK in January 2019. TIV-HD contains 4 times the amount of antigen contained in standard-dose inactivated flu vaccines (60 micrograms as opposed to 15 micrograms). The additional antigen content is intended to enhance the immune response to counter the effect of immunosenescence (age-related reduction in immune response) in those aged 65 and over. Data from one US study showed that among adults aged 65 years of age
and older, the high-dose vaccine induced significantly higher levels of antibodies and was much more effective in preventing flu compared to a standard-dose vaccine\textsuperscript{7}.

TIV-HD was approved for use in the US in 2009 and has been proven to be safe and effective. It is a trivalent vaccine (containing two subtypes of Influenza A (H3N2 and H1N1pdm00) and one type B virus and it is made using an egg-based manufacturing process.

JCVI have advised that this high dose vaccine is suitable for use in those aged 65 years and over. \textbf{However, because of a significantly higher list price TIV-HD is not eligible for reimbursement under the NHS flu vaccination programme.}

\textbf{Which vaccine should be given to adults age 65 years and over}

Three vaccines (aTIV, QIVc and HD-TIV) are available for the 2019/20 flu season for adults age 65 years and over. Evidence suggests that these three vaccines are all superior to standard egg-based inactivated trivalent and quadrivalent vaccines (TIVe/QIVe) in terms of effectiveness for those aged 65 years and over.

There is not enough evidence to express a preference for the use of any single vaccine to date. Therefore, all three are advised by the JCVI as being equally suitable for use in 2019/20, but only two (aTIV and QIVc) will be reimbursed by the NHS. Provided a patient is offered a recommended vaccine for their age, providers are not expected to have to offer a choice between vaccine\textsuperscript{1}.

\textbf{Which vaccine should be given to adults age 18 years to under 65 years in clinical risk groups (including pregnant women)}

Both the QIVe and QIVc vaccines are recommended for adults age 18 years to under 65 years in clinical risk groups for the 2019/20 flu season. Quadrivalent vaccines are recommended as these may provide better protection against the circulating flu B strain(s) which are more likely to affect this younger patient group than older people. Evidence to date suggests that QIVc is as effective in this patient group as QIVe. Although there may be a potential advantage to the use of QIVc as there is no risk of egg adaptation causing a reduction in vaccine effectiveness, the JCVI have said that the evidence of superior effectiveness was not of sufficient quality to express a preference for the use of QIVc at this time. \textbf{Therefore both QIVe and QIVc are advised by the JCVI as being equally suitable for use in 2019/20.} Provided a patient is offered a

recommended vaccine for their age, providers are not expected to have to offer a choice between vaccines¹.

Flu vaccination for healthcare workers aged 65 years old and over

In the healthcare setting, where it is easier to procure only one vaccine and where most recipients are aged under 65 years, it is acceptable to offer QIVe to the small number of staff aged over 65 years if QIVc or aTIV is not readily available. Most healthcare workers are likely to be under 75 years of age and relatively healthy, and should therefore derive benefit from the QIV whether it is cell-based or egg-grown. Immunisers should make it clear to staff aged 65 years and over that they can get the vaccine recommended for their age group (aTIV or QIVc) from their GP or a pharmacy should they wish to. Those aged 65 years and over with underlying medical conditions that make them less likely to respond to standard vaccines should be encouraged to go to their GP or pharmacy to get aTIV or QIVc instead.

Flu vaccination for healthcare workers aged under 18 years old

In the healthcare setting, where it is easier to procure only one vaccine and where most recipients are aged 18 years and over, it is acceptable to offer QIVe or QIVc to the small number of staff under 18 years of age to ensure high coverage. Staff under 18 years of age in an at-risk group, who are not contraindicated to receive the live attenuated influenza vaccine (LAIV), will need to be immunised with LAIV in their GP surgery. Those not in an at-risk group may be vaccinated with QIV under their employer’s occupational health provision. The effectiveness of LAIV and QIV for young people in this age group (16 and 17 year olds) is likely to be equivalent.

Pregnancy

All pregnant women should be offered an inactivated quadrivalent influenza vaccine whilst pregnant, regardless of their stage of pregnancy. Influenza infection during pregnancy may be associated with perinatal mortality, prematurity, lower birth weight and smaller neonatal size. Studies have demonstrated that pregnant women can safely receive influenza vaccine during pregnancy and that infants also receive some protection from maternal antibodies as a result of their mother having the vaccination whilst pregnant.

Pregnant women can access flu immunisation from their GP practice or a community pharmacy. In addition, local NHS England teams have commissioned maternity providers to provide flu immunisation covering over 80% of maternity services.
Vaccination of women who become pregnant late in the flu season

Women who become pregnant during the flu season should be offered influenza vaccine as soon as possible. The timing of the flu season varies each year but usually commences later in December or in the New Year, followed by two to three months of flu transmission. Although the vaccine takes around two weeks to work, pregnant women and their unborn babies are at higher risk of influenza associated morbidity and mortality and should still benefit from vaccination throughout the remaining season.

Administering influenza vaccine at the same time as whooping cough (pertussis) containing vaccine and/or anti-D immunoglobulin

Pregnant women should be offered the flu vaccine as soon as the vaccine becomes available, regardless of their stage of pregnancy. Influenza vaccine should not be deferred in order to give it at the same appointment as pertussis containing vaccine for pregnant women.

Pertussis containing vaccine is recommended for all pregnant women from 16 weeks of pregnancy but is generally offered at around 20 weeks. It is not recommended that pregnant women wait until they reach 20 weeks of pregnancy before having their flu vaccine as this would leave them and their unborn baby at risk of potentially severe illness if they develop influenza.

The injected influenza and pertussis containing vaccines are both inactivated vaccines and so can be administered at the same time, same day or with any interval between them and both should be given at the recommended stage of pregnancy (from 16 weeks for pertussis containing vaccine and at any stage of pregnancy for influenza vaccine).

Anti-D immunoglobulin, where required, can also be given at the same time as or at any interval before/after the flu and whooping cough vaccines.

Administering influenza vaccine to breastfeeding women

Inactivated flu vaccine can be given to breast-feeding women, including those who may also be pregnant or in a clinical risk group. However, breast-feeding is not a clinical indication for influenza vaccination.
Medical conditions

Immunosuppression

The inactivated influenza vaccine can be safely given to immunosuppressed individuals though they may have a suboptimal response to the vaccine.

Individuals may be immunosuppressed because of a medical condition or because of medical therapy that they are taking. As these patients are at risk of increased morbidity and mortality if they develop influenza, they should be offered the vaccine as soon as stock is available. Immunosuppression may continue for several months following completion of treatment. If there is any uncertainty regarding an individual’s level of immunosuppression, further advice should be taken from their consultant.

Patients taking steroid medication

Patients taking steroids can be safely vaccinated with inactivated flu vaccine. As systemic steroids at a dose equivalent to prednisolone 20mg or more per day are considered to be immunosuppressive, patients taking steroids are at risk of serious illness if they develop flu and so should be vaccinated. Patients who are receiving high-dose steroids may be immunosuppressed for at least 3 months after cessation of treatment.

Patients having chemotherapy

Patients receiving chemotherapy should receive their flu vaccine at the earliest opportunity. For individuals due to commence immunosuppressive treatments, inactivated vaccines should ideally be administered at least two weeks before commencement. In some cases this will not be possible and therefore vaccination may be carried out at any time.

Patients taking checkpoint inhibitors

There is no evidence of an association between this adjuvant and autoimmune disease or of any potential risk of enhanced risk of autoimmune disease with adjuvanted vaccine in those given checkpoint inhibitors. The national policy therefore remains in place for use of recommended inactivated flu vaccination. Alternative recommended vaccines without adjuvant are expected to continue to be available for each age group in future seasons. These vaccines should be used if there is clinician decision to use an alternative to an adjuvanted vaccine in those on checkpoint inhibitors. In 2019/20 for those over 65s this includes QIVc and TIV-HD. This is based on poor effectiveness for
standard inactivated vaccines in over 65s, particularly against H3N2. As GPs cannot be reimbursed for the use of HD vaccine, the hospital may have to source it themselves.

Further advice regarding vaccination of immunosuppressed individuals can be found in Chapter 7 of the Green Book.

Vaccine ordering and supply

Given that some influenza vaccines are restricted for use in particular age groups, the Summary of Product Characteristics (SPCs) for individual products should always be referred to when ordering vaccines to ensure that they can be given appropriately to particular patients or patient age groups.

General Practices and Community Pharmacists are responsible for ordering sufficient inactivated influenza vaccine for all eligible patients aged 18 years and over directly from the manufacturer. A list of vaccines available for the 2019/20 flu programme is contained in the 2019/20 annual flu programme letter. More information about vaccine ordering is given on the NHS England webpage, Vaccine ordering for 2019-20 influenza season: letters.

All influenza vaccines for children aged 6 months to less than 18 years are purchased centrally by Public Health England and should be ordered via ImmForm. This includes LAIV, and inactivated vaccines for children in a clinical risk group for whom the LAIV is medically contraindicated or otherwise unsuitable. For the 2019/20 flu season, PHE has purchased the egg-grown quadrivalent influenza vaccine (QIVe) for children aged 6 months to less than 2 years, and for those 2 years or above in whom LAIV is contraindicated.

With the exception of flu vaccines for the children’s programme which are centrally procured, the supply of influenza vaccine to community pharmacies and general practices is a private transaction between the individual provider and their vaccine supplier.

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Accessing additional stock

Additional vaccines for adults should be ordered directly from any of the vaccine manufacturers. Practices are advised to review their current orders with their suppliers and ensure they have ordered sufficient stock to vaccinate their eligible patient population.

Vaccine storage and handling

Storage of inactivated influenza vaccine

Inactivated influenza vaccines should be stored between 2°C and 8°C and should be stored in the original packaging to protect the vaccine from light. Vaccine should not be removed from the cold chain until it is required for use.

Vaccine storage incidents

Should vaccines be inadvertently stored outside the recommended temperature range of 2°C to 8°C, the vaccine should be quarantined, and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to the Vaccine Incident Guidance document\(^9\) and seek further advice on vaccine stability and cold chain storage incidents from your local screening and immunisation team (www.england.nhs.uk/about/regional-area-teams/).

Influenza vaccine components

Vaccine antigens

Each year, the World Health Organisation (WHO) monitors the epidemiology of influenza across the world and makes recommendations to vaccine manufacturers regarding the strains of influenza to include in the vaccine\(^10\).

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For the 2019/20 flu season (northern hemisphere winter), it is recommended that quadrivalent vaccines contain the following:

- A/Brisbane/02/2018 (H1N1)pdm09-like virus
- A/Kansas/14/2017 (H3N2)-like virus
- B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage)
- B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage)

This vaccine composition differs from the 2018/19 vaccine composition as both influenza A strains have been replaced.

The influenza B component in the 2019/20 trivalent vaccines (aTIV and TIV-HD) will be the B/Colorado/06/2017-like virus of the B/Victoria/2/87-lineage⁹.

Egg (ovalbumin) content

Some of the inactivated influenza vaccines (QIVe) may contain traces of egg such as the egg protein ovalbumin. A table stating the ovalbumin content of the flu vaccines for the 2019/20 season is available on p16 of the National flu immunisation programme 2019 to 2020 letter¹ and is also available as a separate document: Influenza vaccines: 2019 to 2020 flu season on the PHE Annual flu programme webpage.

With the exception of those individuals with a severe anaphylaxis to egg which has previously required intensive care, patients with less severe egg allergy can be immunised in any setting using an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to 0.06 micrograms in a 0.5 ml dose) or using the egg-free cell-based quadrivalent influenza vaccine (QIVc), Flucelvax Tetra (licensed from 9 years of age).

The aTIV vaccine, Fluar, contains more than the recommended ovalbumin content for patients with egg allergy (each 0.5ml dose contains less than or equal to 0.2 micrograms ovalbumin). Patients aged 65 years and over with an egg allergy should therefore be given the egg-free cell-based quadrivalent influenza vaccine (QIVc), Flucelvax Tetra.

Patients with a previous severe anaphylactic reaction to egg

Patients with severe anaphylaxis to egg who have previously required intensive care should be referred to specialists for immunisation in hospital or, if 9 years of age or over, should be given the egg-free cell-based quadrivalent influenza vaccine (QIVc), Flucelvax Tetra. If there is any uncertainty about the cause of an anaphylactic reaction, the patient should be advised to consult with an immunologist.
Further information about egg allergy and influenza vaccine can be found in the Influenza chapter 19 of the Green Book.

Vaccine adjuvant in aTIV

Vaccine adjuvants can reduce the amount of virus required for the production of a vaccine but they are primarily added to vaccines to enhance and lengthen the duration of the immune response.

This is particularly important for those aged 65 years and older as the ageing immune system may result in a suboptimal response to influenza vaccine and there is evidence of limited effectiveness of standard trivalent vaccines in those aged 65 years and over.

The aTIV vaccine (Fluad) contains an adjuvant called MF59 which improves the immune system’s response to vaccination and helps it to produce more antibodies against the influenza virus strains in the vaccine. MF59 is an oil-in-water emulsion of squalene oil, polysorbate 80, sorbitan trioleate, sodium citrate, citric acid and water for injections. Squalene is a naturally occurring substance that is found in humans, animals and plants. In humans, it is made in the liver and circulates in the bloodstream. Squalene is also found in a variety of foods, cosmetics, over-the-counter medications and health supplements. The squalene used in pharmaceutical products and vaccines is commercially extracted from fish oil and is then highly purified during the manufacturing process.

A single dose of Fluad contains less than 10mg of squalene. To put this in context, over 1000mg of squalene is made in the liver every day, and humans ingest around 50mg to 200mg of squalene every day in a normal diet.

Polysorbate 80, sorbitan trioleate and sodium citrate are emulsifiers which stop the squalene oil from separating out of the water in the vaccine. These, along with citric acid (also contained in the adjuvant) are all commonly used in foods and drinks.

The squalene in the Fluad vaccine is obtained from the spiny dog fish and shark liver oil forms around 80% of the squalene for MF59. Fluad vaccine is not tested for residual fish protein and there is no data available as to whether or not residual fish protein remains in the vaccine following the purification process. Patients who report

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11 Centers for Disease Control and Prevention. FLUAD™ Flu Vaccine With Adjuvant. Available at: www.cdc.gov/flu/protect/vaccine/adjuvant.htm
12 World Health Organization. Squalene-based adjuvants in vaccines. Available at: www.who.int/vaccine_safety/committee/topics/adjuvants/squalene/questions_and_answers/en/
13 Personal communication from Seqirus. 8 June 2018
14 Personal communication from Seqirus October 2019
hypersensitivity to fish should be assessed as to the nature and severity of their allergy before the vaccine is given.

**Latex**

The influenza vaccines for 2019/20 are not contraindicated in latex allergic individuals. The vaccine components that are in contact with the injection solution/suspension are latex-free. As identified in the case of Fluarid in the 2018/19 season, some vaccines may be supplied with needle shields that are not latex-free. Summary of Product Characteristics are not required to provide warnings where the needle shield may contain latex and the risk of contamination from latex proteins from the needle sheath into the vaccine is considered negligible by experts. Individuals, including those with a latex allergy, are therefore recommended to receive an influenza vaccine recommended for them in accordance with their age.

As with all vaccines, immunisers must be trained in the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given.

**Antibiotics**

Some inactivated flu vaccines may contain residues of antibiotics which are used during the vaccine manufacturing process. For example, Fluarid may contain residues of the antibiotics kanamycin and neomycin sulphate so patients with a severe / anaphylactic kanamycin or neomycin sulphate allergy should be offered an alternative vaccine.

Flucelvax Tetra does not contain any antibiotics. The way in which it is made (grown in cells, not eggs) means that there is no need to use antibiotics during the manufacturing process.

**Other additives**

The Vaccine Knowledge Project Inactivated Flu Vaccine webpage\(^{15}\) contains lots of useful information about the constituents of inactivated flu vaccines.

**Suitability of QIVc for vegetarians and vegans**

The original cells used in the Madin-Darby Canine Kidney (MDCK) cell line in which the flu vaccine viruses used in QIVc are grown were taken by Madin and Darby from the kidney tubule of an adult dog in 1958. This is the cell line that is still used today. It is a

\(^{15}\) Oxford Vaccine Group. Vaccine Knowledge Project. Inactivated Flu Vaccine webpage: [vk.ovg.ox.ac.uk/inactivated-flu-vaccine](http://vk.ovg.ox.ac.uk/inactivated-flu-vaccine)
continuous cell line where the cells have adapted to grow and divide continually with unlimited availability so the cell-based manufacturing process does not require any new cells to be taken\textsuperscript{16}.

After the vaccine viruses are grown, they are highly purified and this purification process removes the cell culture materials. It is extremely unlikely that any cell culture material remains in the vaccine (the risk of a dose of the final vaccine product containing an intact MDCK cell is calculated to be less than 1 per 10\textsuperscript{34} doses\textsuperscript{17}).

The MDCK cell line is used because the influenza virus grows well in it, it is able to produce high volumes of flu virus for use in vaccines and the influenza virus isolated following culture in these cells retains the antigenic properties of the original strain. So this method of vaccine virus production should result in the vaccine virus being a closer match to the wild-type circulating flu viruses.

Although previous versions of this document stated that gelatin is used during the filtration process of QIVc and that it was possible that a residual amount of gelatin may be introduced into the vaccine at this time, the manufacturers have recently advised that gelatin is not added to the final vaccine product or used during the manufacture of Flucelvax Tetra\textsuperscript{18}.

Suitability of QIVc for those with a history of allergy to canine allergens

A history of hypersensitivity to canine allergens is not listed as a contraindication or precaution to immunisation with Flucelvax Tetra (QIVc). MDCK cells do not express known major canine allergens associated with hypersensitivity reactions; however minor canine allergens may be present, posing a hypothetical concern about the possibility of hypersensitivity reactions. In clinical trials (totaling over 10,000 participants), none of the participants who reported a dog allergy reported any hypersensitivity reactions following administration of QIVc. There was no indication of any increased incidence in immediate local or systemic reactions in those who received Flucelvax compared to those who received an egg-grown influenza vaccine or who were in the placebo groups\textsuperscript{15}. If there is significant concern, patients can be given an egg-grown vaccine instead.

\textsuperscript{16} Personal communication from Seqirus. 7 May 2019
\textsuperscript{17} Gregersen JP, Schmitt HJ, Trusheim H et al. Safety of MDCK cell culture-based influenza vaccines. Future Microbiol. 2011 Feb;6(2):143-52
\textsuperscript{18} Personal communication from Seqirus. 5 November 2019
Vaccine dose

Inactivated influenza vaccines contain 0.5ml of vaccine. JCVI has advised that where alternative doses are given in the manufacturer’s Summary of Product Characteristics (SPC), the 0.5ml dose of intramuscular inactivated influenza vaccine should be given to infants and young children aged six months and older because there is evidence that this dose is effective in young children.

Children under nine years of age who are in a clinical risk group but have never previously received influenza vaccine should be offered two doses of influenza vaccine with a four week interval between them.

Children in a clinical risk group who have received one or more doses of influenza vaccine in previous flu seasons should be considered as previously vaccinated and only require a single dose of influenza vaccine each season.

All others eligible to receive an influenza vaccine, including pregnant women and those aged 65 years and over, should receive a single 0.5ml dose each season they are eligible.

Contraindications and precautions

The inactivated influenza vaccine is contraindicated for all patients who have had:

- an anaphylactic reaction to a previous dose of the vaccine
- an anaphylactic reaction to any of the vaccine components (other than ovalbumin – see section on egg content above)

For a full list of influenza vaccine components, please see the manufacturer’s Summary of Product Characteristics (SPC) available on the Electronic Medicines Compendium website. The SPC for individual products should be referred to when assessing the suitability of the vaccine for the patient (for example if they have an egg or antibiotic allergy).

Temporary deferral of immunisation

If there is evidence of current neurological deterioration, temporary deferral of vaccination may be considered to avoid incorrect attribution of any change in the underlying condition. The risk of deferring the vaccine should be balanced against the
risk of flu and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

This precaution does not apply to individuals with a chronic neurological condition who should be offered vaccine once vaccine stock becomes available.

Patients who are acutely unwell when presenting for vaccination

Vaccination may be postponed in those who are acutely unwell until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.

Guillain-Barré Syndrome (GBS) and influenza vaccine

Previous GBS is not a contraindication to influenza vaccination. A UK study found that there was no association between GBS and influenza vaccines although there was a strong association between GBS and influenza-like illness. A causal relationship between immunisation with influenza vaccine and GBS has not been established.

PGDs and Written Instructions

PHE have developed a Patient Group Direction (PGD) template for inactivated flu vaccine to support the administration of inactivated influenza vaccine. The PGD is not legally valid until it has had the relevant organisational authorisation from an appropriate authorising person in Section 2 of the PGD.

The PGD template covers NHS commissioned services. It does not cover the provision of occupational health schemes or peer-to-peer influenza immunisation. So that organisations can offer employee seasonal flu vaccinations within the legislation, a written instruction for seasonal influenza vaccination has been produced. This is available on the NHS Specialist Pharmacy Service website: Written Instruction for the administration of seasonal ‘flu vaccination.

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Preparing the vaccine

Vaccines in prefilled syringes may contain an air bubble. This should not be expelled unless it is specifically stated to do so in the vaccine SPC. To try to expel it risks accidently expelling some of the vaccine and therefore not giving the patient the full dose. Once injected, the air bubble forms an airlock preventing the vaccine seeping out along the needle track into subcutaneous tissue and onto the skin. The small bolus of air injected following administration of the vaccine clears the needle and prevents a localised reaction to the vaccination.20

Vaccine administration

Influenza vaccine should ideally be offered before influenza viruses start to circulate so the ideal time for immunisation is between late September and end of November. However, as peak influenza activity generally occurs in January or February or sometimes later, providers should continue vaccinating patients throughout the influenza season, as long as they have unexpired vaccine in stock and unvaccinated patients in their practice. Providers should apply clinical judgement, taking into account the level of flu-like illness in their community and the fact that the immune response following flu vaccination takes about two weeks to develop fully.

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 one year and over, the deltoid muscle in the upper arm is the preferred muscle.

Due to the presence of the adjuvant (MF59), Fluad should be administered intramuscularly using a 25mm needle to enable the vaccine to be delivered into the muscle. For the 2019/20 flu season, Fluad is being supplied with a pre-fixed (staked) needle of a suitable size.

Vaccination of patients taking anticoagulants or with a bleeding disorder

There is a lack of evidence that the subcutaneous route of vaccination is any safer than the intramuscular route in people taking anticoagulants. The subcutaneous route can itself 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. A fine needle (equal to 23 gauge or finer calibre) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual’s anticoagulant therapy.

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (equal to 23 gauge or finer calibre) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/parent/carer should be informed about the risk of haematoma from the injection.

The needle provided with the aTIV Fluaq vaccine is 25G (gauge) and is therefore suitable for use for patients taking anticoagulants or with a bleeding disorder.

Influenza vaccines licensed for intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. However, Fluarix Tetra (QIVe), Flucelvax Tetra (QIVc), Fluaq (aTIV) and the Trivalent Influenza Vaccine (Split Virion, Inactivated) High Dose vaccine (TIV-HD) are not licensed for subcutaneous administration so should only be administered intramuscularly. If these vaccines are given subcutaneously in error however, they do not need to be repeated but the vaccinated individual should be warned of the increased risk of local reactions at the injection site.

Reactions following administration of inactivated flu vaccine

Commonly reported reactions following administration of inactivated flu vaccine include: malaise, low grade fever, headache, fatigue, myalgia, arthralgia and redness, swelling.

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21 Centers for Disease Control and Prevention. Vaccine recommendations and guidelines of the ACIP. Vaccinating Persons with Increased Bleeding Risk. Available at: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/special-situations.html
and pain at the injection site. Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur but are rare.

In clinical trials, the incidence of both mild local and systemic reactions following immunisation with aTIV (Fluad) was found to be higher than the incidence of reactions following unadjuvanted TIV vaccines. The CDC website reports that some adverse events were also reported more frequently after vaccination with high-dose flu vaccine than after standard-dose inactivated flu vaccine (although the side effects reported are the same as those reported after standard dose flu vaccines). QIVc (Flucelvax Tetra) is reported to be well tolerated with a similar safety profile to egg-based flu vaccines.

The frequency of injection site pain and systemic reactions may be higher in individuals vaccinated concomitantly with inactivated flu vaccine and pneumococcal polysaccharide vaccine (PPV23) compared to vaccination with influenza vaccine alone and similar to that observed with PPV23 vaccination alone. However, if indicated, flu vaccine and PPV23 can be administered at the same visit in different limbs.

**Reporting of adverse reactions**

Healthcare professionals and patients/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme: yellowcard.mhra.gov.uk

The quadrivalent cell cultured inactivated influenza vaccine (QIVc), quadrivalent egg-grown inactivated influenza vaccines (QIVe) and high-dose trivalent inactivated influenza vaccine (TIV-HD) carry a black triangle symbol (▼). Therefore, any suspected adverse reactions should be reported via the Yellow Card Scheme.

Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.

**Patients who have already received an influenza vaccine during early 2019**

If the patient received the vaccine produced for the 2018/19 season, then they will still need a dose of the vaccine produced for the 2019/20 season as it contains different viruses to protect against other influenza strains.

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24 Joint Committee on Vaccination and Immunisation Ad-hoc flu subcommittee. Minutes of meeting 14 September 2018. Available at: [app.box.com/s/iddfb4ppwkmj1jysir2tc/file/349905031141](http://app.box.com/s/iddfb4ppwkmj1jysir2tc/file/349905031141)
In addition, the protection gained from flu vaccine is only thought to last for one season so those eligible to receive the vaccine are recommended to have it every season to ensure on-going protection.

If a patient has received a vaccine in 2019 formulated for the southern hemisphere (eg because they were in Australia, New Zealand etc during the flu season there), and they will be in the UK (northern hemisphere) over winter 2019/20, they should receive another dose of vaccine in the UK as the vaccine formulated for the northern hemisphere for the 2019/20 flu season contains different strains than the one given in the southern hemisphere in 2019.

**Individuals who have inadvertently been given a flu vaccine that is not the one recommended for their age group**

If an individual has inadvertently received a flu vaccine different to the one recommended for their age group, they should be informed of the error and the potential implications of this error. Although QIVe, QIVc, aTIV and TIV-HD should provide some protection against flu in all age groups, individuals aged 65 years and over (particularly those more than 75 years of age) may not respond as well to the QIVe as they would to the vaccines recommended for their age group (QIVc, aTIV, TIV-HD), and individuals aged under 65 years will not benefit from the opportunity to make protection against an additional flu strain if they have been given aTIV or TIV-HD.

If the individual wishes to receive the vaccine that they should have been given, this can be offered following a discussion of the benefits and risks. The clear benefit is the additional protection that may be offered by the correct vaccine but they should be alerted to the potential increased risk of a local or systemic reaction. Although there is no data available on the safety and effectiveness of administering a second flu vaccine shortly after the first in adults, this advice is based on general principles of vaccination, experience of flu revaccination following cold chain and administration incidents and information about the high dose flu vaccine which has previously been used in the United States (as it contains four times the amount of antigen that is in a single dose of QIV or aTIV).

If a decision is made to offer the vaccine the individual should have received, it is recommended that this is done as soon as possible after the first dose was given and ideally within a week. This will enable protection to be made as soon as possible. It can still be given if more than a week has elapsed however.

**Patients under 65 years of age at time of vaccination but who will be 65 years old by 31st March 2020**
Although it is stated in the SPC for Fluad (aTIV) that this vaccine is indicated for patients aged 65 years and over, patients who will become 65 years of age by 31\textsuperscript{st} March 2020 but who are 64 years at the time of vaccination can receive aTIV off-label in accordance with the recommendations for the national influenza immunisation programme for 2019/20\textsuperscript{1}. This off-label use is covered in the PHE national template PGD for inactivated influenza vaccine.

Uncertainty regarding previously administered dose of influenza vaccine

If there is no documented evidence of an eligible patient having a flu vaccine during the current flu season then they should be offered a dose. If they have already had one this flu season, an additional dose is unlikely to cause any harm. Any adverse reactions to an extra dose are likely to be similar to those commonly seen after a first dose of flu vaccine such as local redness/pain at the injection site, malaise etc.

Inadvertent administration of a second dose of influenza vaccine

Any adverse reactions to an extra dose are likely to be similar to those commonly seen after a scheduled first dose of flu vaccine such as local redness/pain at the injection site, malaise etc. The patient should be advised of this and offered reassurance that patients under the age of nine years who have never received influenza vaccine in previous years are specifically recommended to have two doses four weeks apart. Local systems should be reviewed to prevent this happening again.

Incomplete dose of vaccine given

If it is thought that the patient did not receive a full dose of vaccine (for example, because some spilt out whilst administering the vaccine), it is recommended that the dose is repeated. This can be at any interval from the partial dose already given. Giving it the same day or within the next few days will enable protection to be made as soon as possible but the patient should be informed there may be a potential risk of local and systemic reactions from a repeat dose.

Vaccination of patients recently diagnosed with influenza infection

Individuals eligible to receive the influenza vaccine should have it even if they have recently had confirmed influenza infection. Having the vaccine will help to protect against other circulating strains. Both the inactivated flu vaccine and the LAIV can be given at any time following recovery providing there are no contraindications to vaccination and the patient is not acutely unwell.
Administering inactivated influenza vaccine at the same time as other vaccines or immunoglobulins

The inactivated influenza vaccine can be given at the same time as, or at any interval before or after, any immunoglobulin or other vaccine (whether live or inactivated). The vaccines should be given at separate sites, preferably in different limbs but if given in the same limb, they should be given at least 2.5cm apart and the site of each should be recorded in the patient’s record. Because of the increased risk of local reaction following aTIV and TIV-HD, these vaccines should be administered in a separate limb to any other vaccines that need to be given at the same time.

Inadvertent administration of expired doses of vaccine

Vaccines from previous years programmes should be discarded before stock for the current year is received.

As new flu vaccine stock is purchased each year, it is unlikely that a patient will receive a dose that has expired. However, in the event that this occurs, an additional dose with a valid expiry date should be offered. This can be given at any interval from the expired dose but should preferably be given the same day or as soon as possible in order not to delay protection.

Patients previously eligible for influenza vaccine but who are no longer in a risk group

Some patients may have had the vaccine during previous flu seasons whilst in an at-risk group but may no longer be in that group. Examples could include women who were pregnant during the last flu season but are not pregnant during this flu season or patients who were taking regular steroids during last flu season but are no longer taking them.

Providing that these patients are not in any other risk group described in the Green Book or annual flu letter, they would not be eligible for flu vaccination this year. However, the Green Book states that clinicians should exercise professional judgement when assessing a patient and can recommend vaccination for individuals, even if they are not in a listed risk group, if influenza is likely to exacerbate their underlying condition.

Patients requesting live intranasal influenza vaccine (LAIV) instead of an inactivated injected vaccine due to needle phobia

Patients for whom the inactivated injected vaccine is recommended should be encouraged, where possible, to have the inactivated injected vaccine.
LAIV is not licensed in adults because there is some evidence of poorer efficacy when compared with the inactivated vaccine.

However, individual medical practitioners may choose to use LAIV ‘off-label’ for adults, without any other medical contraindication, who are eligible for influenza vaccination but who cannot be vaccinated with injectable vaccines. This could include patients with learning disabilities who become seriously distressed with needles. See Flu vaccinations: supporting people with learning disabilities for more information.

The legislation does allow for such situations and the Medicines and Healthcare products Regulatory Agency state that ‘there are clinical situations when the use of medicines outside the terms of the licence (ie, ‘off-label’) may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence.’ The responsibility for such use rests with the health professional. In this situation, a Patient Specific Direction (PSD) will be required. In these exceptional circumstances, where it has not proved possible to administer the inactivated vaccine, PHE has agreed that the national LAIV stock can be used for this purpose.

Useful links

**Letter detailing 2019/20 flu programme**

**Immunisation against infectious disease (the Green Book) Influenza chapter 19.**

**Leaflets, posters and training slides** prepared specifically to support the annual flu programme. Available at: www.gov.uk/government/collections/annual-flu-programme

**Additional flu resources** available at: www.gov.uk/government/collections/annual-flu-programme

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The national influenza immunisation programme 2019 to 2020:
Inactivated influenza vaccine - Information for healthcare practitioners

Summary of Product Characteristics (SPC) for flu vaccines are available at www.medicines.org.uk/emc/

PGD templates for flu vaccines
www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

Written Instruction for the administration of seasonal ‘flu vaccination
www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/

Links to other key documents relating to the flu vaccine programme are available on page 5 of The national flu immunisation programme 2019/20 letter available at www.gov.uk/government/publications/national-flu-immunisation-programme-plan

Vaccine Knowledge Project. Inactivated Flu Vaccine. Available at: vk.ovg.ox.ac.uk/inactivated-flu-vaccine


Healthcare Workers Flu Immunisation resources (leaflets, posters, guides and resource packs). Available at: campaignresources.phe.gov.uk/resources/campaigns/92-healthcare-workers-flu-immunisation-/resources