The National Influenza Immunisation Programme 2017/18

Information for Health Care Practitioners about the use of the inactivated influenza vaccine
About Public Health England

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Published July 2017
PHE publications gateway number: 2017248

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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 those aged over 65 years (2000) and pregnant women (2010).

A phased programme commenced during 2013 to offer influenza vaccine to all children from 2 years of age. During the 2017/18 programme, influenza vaccine will be offered to children in at risk groups and to all children two to eight years of age (but not nine years or older) on 31 August 2017. These children will be offered Live Attenuated Influenza Vaccine (LAIV).

One important change in the 2017/18 flu programme is that vaccination of the morbidly obese (defined as BMI of 40 and above) will attract a payment under the directed enhanced services (DES).

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

1. The Enhanced service specification for the influenza and pneumococcal vaccination programmes 2017/18 describes the services to be provided by GP practices delivering the programme in England.
2. The Flu Plan for 2017/18 sets out an evidence based approach to planning for the flu programme
3. The National flu immunisation programme 2017/18 letter provides detailed information to support the successful implementation of the programme
4. The Green Book Influenza chapter 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.

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

Influenza

Influenza infection

Influenza is a highly infectious, acute viral respiratory tract infection which has a usual incubation period of one to three days. Patients can experience sudden onset of symptoms such as dry cough, headache, fever and extreme fatigue.4

There are three types of influenza virus: 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 two to seven days.

Risk groups for influenza infection

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.4

Influenza during pregnancy may also be associated with perinatal mortality, prematurity, lower birth weight and smaller neonatal size.

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.
Protection can occur in two ways:-

- direct protection occurs when an individual is vaccinated so they develop their own immunity
- indirect protection occurs when a large number of the population are vaccinated. This lowers flu transmission and thereby provides some protection to older adults and people with clinical risk factors who may have a sub-optimal response to their own immunisation

**Inactivated flu vaccine**

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.

Influenza vaccines can be inactivated or live attenuated and, depending upon the vaccine and the manufacturer’s recommendations, they may be administered by intramuscular injection (inactivated), intradermal injection (inactivated) or by intranasal application (live).

Most of the inactivated vaccines available in the UK are trivalent, containing two subtypes of Influenza A virus and one of Influenza B virus. Quadrivalent vaccines are also available which contain two subtypes of A virus and two subtypes of B virus.

For the 2017/18 flu season (northern hemisphere winter) it is recommended that trivalent vaccines contain the following:

- an A/Michigan/45/2015 (H1N1)pdm09-like virus;
- an A/Hong Kong/4801/2014 (H3N2)-like virus; and
- a B/Brisbane/60/2008-like virus.

Quadrivalent vaccines should contain the above three viruses and a B/Phuket/3073/2013-like virus

GPs can purchase from a range of inactivated influenza vaccines. A full list of vaccines available for the 2017/18 flu programme is contained in the 2017/18 flu letter3.
The inactivated influenza vaccine is recommended for:

- children aged six months to two years in an at risk group
- children aged two to less than 18 years with a contraindication to the live attenuated influenza vaccine (LAIV)
- those aged 18 years and over in an at risk group
- pregnant women
- those aged 65 years and older
- those in long-stay residential care homes
- carers

Further details of those eligible to receive the vaccine can be found in Chapter 19 of the Green Book and in the Annual flu letter for 2017/18.

Dosage

Infants and children aged six months to two years and over when LAIV is contraindicated

Some of the Summary of Product Characteristics (SPCs) for inactivated influenza vaccines indicate that infants aged six months and over and young children can be given either a 0.25ml dose or a 0.5ml dose. JCVI has advised that where alternative doses are given in the SPC, the 0.5ml dose of intramuscular inactivated influenza vaccine should be given to infants and young children aged six months and older.

Children under nine years of age who are in a clinical risk group and require inactivated influenza vaccine (due to the LAIV being contraindicated) but have never previously received influenza vaccine should be offered two doses of the vaccine with a four week interval between them.

Children who are in a clinical risk group and require inactivated influenza vaccine (due to the LAIV being contraindicated) but 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 vaccine.

All others eligible to receive the inactivated flu vaccine, including pregnant women and those aged 65 years and over should receive a single 0.5ml dose.
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).

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.

In addition, the SPC for individual products should be referred to when deciding which vaccine to give.

Vaccine constituents

Egg (ovalbumin) content

Inactivated influenza vaccines may contain traces of egg such as ovalbumin. Adults with egg allergy can be immunised in any setting using an inactivated flu vaccine with an ovalbumin content less than 0.12 µg/ml (equivalent to <0.06µg for 0.5ml dose). There is no ovalbumin-free vaccine available for the 2017/18 flu season.

The ovalbumin content of the flu vaccines for the 2017/18 season is published in the July 2017 edition of Vaccine Update.

Patients with a previous anaphylactic reaction to egg

Adults with severe anaphylaxis to egg who have previously required intensive care should be referred to specialists for immunisation in hospital.

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 the inactivated influenza vaccine can be found in the Influenza chapter 19 of the Green Book.
Vaccine ordering, storage and handling

Several vaccine manufacturers produce inactivated influenza vaccines each year. Some influenza vaccines are restricted for use in particular age groups. The Summary of Product Characteristics (SPC) for individual products should always be referred to when ordering vaccines for particular patients.

A full list of influenza vaccine manufacturers with their contact details is included in the national flu immunisation programme 2017/18 letter for 2017/18.

Ordering inactivated influenza vaccine

General Practices are responsible for ordering sufficient inactivated influenza vaccine for all eligible patients aged 18 years and over directly from the manufacturer. It is recommended that orders are placed with more than one manufacturer in case of supplier delays or difficulties in the manufacture or delivery of the vaccine.

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 for whom the LAIV is contraindicated.

Accessing additional stock

Additional vaccines should be ordered directly from any of the vaccine manufacturers.

National reserve of vaccine stock

There will be no national reserve of vaccines to order from this year. Practices are advised to review their current orders with their suppliers and ensure they have ordered sufficient stock to vaccinate their eligible patient population.

Storage of inactivated influenza vaccine

Inactivated influenza vaccines should be stored in their original packaging between 2°C and 8°C.
Vaccine storage incidents including cold chain issues

Should vaccines be inadvertently stored outside the recommended temperature range of 2°C to 8°C, you should refer to the Vaccine incident guidance document and the vaccine product’s Summary of Product Characteristics. Further advice should be obtained from your local screening and immunisation team (https://www.england.nhs.uk/about/regional-area-teams/).

Vaccine administration

The inactivated influenza vaccine should be administered as an intramuscular injection (except for Intanza® vaccine). For infants aged six months to one year, the anterolateral aspect of the thigh can be used. For all of those aged one year and over, the deltoid is the preferred muscle.

Patients that have already had an influenza vaccine during early 2017

If the patient received the vaccine produced for the 2016/17 season then they will still need a dose of the vaccine produced for the 2017/18 season.

The vaccine for 2017/18 contains a different strain from the previous year. During the 2016/17 season, the vaccine contained protection against A/California/7/2009 (H1N1)pdm09-like virus. This has been replaced with A/Michigan/45/2015 (H1N1)pdm09-like virus for the 2017/18 season.

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 year to ensure on-going protection.

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. Even if they have already had one this flu season an additional dose is unlikely to cause any harm. Any adverse reaction to an extra dose is likely to be similar to those commonly seen after a dose of flu vaccine such as local redness/pain at the injection site, malaise etc.
Inadvertent administration of a second dose of influenza vaccine

It is not harmful to have extra doses of the inactivated flu vaccine if given inadvertently. Any adverse reaction to an extra dose is 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 offered reassurance and local systems reviewed to prevent this happening again.

Vaccination of patients recently diagnosed with influenza infection

Anyone 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 influenza 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.

Inadvertent administration of expired doses of vaccine

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. Giving an additional dose will not cause any harm and will ensure that the individual benefits from vaccination. This can be given at any interval from the previous dose.

Vaccination of patients with bleeding disorders or taking anticoagulants

If the patient has a bleeding disorder and is eligible to receive the influenza vaccine then they should be offered it at the earliest opportunity. The vaccine should be administered by deep subcutaneous injection to individuals with bleeding disorders to minimise the risk of bruising or bleeding.

In contrast, most patients on stable anticoagulant therapy can receive influenza vaccine by intramuscular injection, for example individuals on warfarin who are up-to-date with their scheduled INR testing and where their latest INR was in the therapeutic range.
For other patients at risk of bleeding, most influenza vaccines are licensed for administration by either the intramuscular or subcutaneous routes.

Recommendations for subcutaneous vaccine administration for patients on anticoagulants are based on the theoretical risk of haematoma. There is a lack of primary source evidence to support the hypothesis that the subcutaneous route of vaccination is any safer than the intramuscular route in people taking anticoagulants and the subcutaneous route can itself be associated with an increase in localised reactions.

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. The air bubble is also there for a reason – the air injected into the muscle 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.

Optimum time for offering influenza vaccine

Influenza vaccine should ideally be offered before influenza viruses start to circulate so the ideal time for immunisation is between September and early 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.

Pregnancy

All pregnant women should be offered an inactivated influenza vaccine whilst pregnant, regardless of their stage of pregnancy. 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.
Administering influenza vaccine at the same time as whooping cough (pertussis) containing vaccine and/or anti-D immunoglobulin

The injected flu vaccine and whooping cough (pertussis) containing vaccine are both inactivated vaccines so can be given on the same day or with any interval between them. Pregnant women should be offered the flu vaccine as soon as the vaccine becomes available in the practice, regardless of the stage of pregnancy as immunity can take around 14 days to develop. Influenza vaccine, whooping cough vaccine and anti-D immunoglobulin can all safely be given at the same time or with any interval between them.

Do not defer influenza vaccination in order to give with the pertussis containing vaccine

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. Influenza and pertussis containing vaccines can be administered at the same time 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).

Administering influenza vaccine to breastfeeding women

Flu vaccine can be given to breast-feeding women if they are pregnant or in an at 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 sub optimal 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 a number of 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 safely be 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.

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

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 inhaled 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 with neurological conditions

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, 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 generally 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 but the Summary of Product Characteristics should always be referred to when deciding which vaccine to give. 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 established5.

Patients with a learning disability

Clinicians are advised to conduct a clinical assessment on patients with a learning disability to determine whether they have a condition that places them at higher risk of severe disease following flu infection.

Patients requesting live intranasal influenza vaccine (LAIV) instead of the inactivated injected one 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.

Individual medical practitioners may choose to use LAIV “off-label” for adults, without any other medical contra-indication, who are eligible for influenza vaccination but who cannot be vaccinated with injectable vaccines. This could include patients with learning difficulties who become seriously distressed with needles.

The legislation does allow for such situations and states that ‘prescribers can use unlicensed and off-label medicines where there is no suitable alternative.’ The responsibility for such use rests with the health professional. In this situation, a patient specific direction 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.

In previous years, an intradermal inactivated influenza vaccine (Intanza®) has been available for those aged 60 years and over. Manufacturers have confirmed that this vaccine will not be available to purchase for the 2017/18 programme.

Resources

**Flu Plan and Supporting Letter detailing 2017/18 flu programme**

**Green Book Influenza chapter 19.** Available at: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
Leaflets, posters, training slides and other resources to support the annual flu programme Available at: https://www.gov.uk/government/collections/annual-flu-programme

To order hard copies of printed leaflets and posters free of charge, go to Flu 2017 on home page of the order line
https://www.orderline.dh.gov.uk/ecom_dh/public/contact.jsf
To order large quantities of posters and leaflets Telephone number: 0300 123 1003

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

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