



NHS England gateway number: 08379

PATIENT GROUP DIRECTION (PGD)

Administration of inactivated influenza vaccine to adults in accordance with the community pharmacy seasonal influenza vaccination advanced service and national influenza immunisation programme.

This PGD is for the administration of inactivated influenza vaccine by pharmacists delivering the community pharmacy seasonal influenza vaccination advanced service.

Reference: Pharmacy Influenza Vaccination PGD
Version no: v05.00
Valid from: 1 September 2018
Expiry date: 31 March 2019

Public Health England (PHE) has developed this PGD for authorisation by NHS England to facilitate delivery of the national immunisation programme.

NHS England and community pharmacy contractors must not alter or amend the clinical content of this document (sections 3, 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. Section 2 may be amended by NHS England only. Section 7 is to be completed by the community pharmacy contractor providing the advanced service.

Operation of this PGD is the responsibility of NHS England as the commissioner and the community pharmacy contractor as the service provider.

A PHARMACIST MUST BE AUTHORISED BY NAME TO WORK ACCORDING TO THE CURRENT VERSION OF THIS PGD BY SIGNING SECTION 7. A MANAGER WITH THE RELEVANT LEVEL OF AUTHORITY SHOULD ALSO PROVIDE A COUNTER SIGNATURE.

Providers must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. The current version of the community pharmacy seasonal influenza vaccination advanced service PGD (Pharmacy Influenza Vaccination PGD) can be found at:

www.england.nhs.uk

Any enquiries regarding this PGD should be addressed to:

ENGLAND.communitypharmacy@nhs.net

Change History

Version number	Change details	Date
V01.00	New PHE PGD template	18 August 2015
V01.00 (National Community Pharmacy Advanced Service)	Front page and page 4 amended to reflect national NHS England authorisation for delivery of the national Community Pharmacy Advanced Service	03 September 2015
V02.00	New Pharmacy Influenza PGD for the 2016/2017 season to replace IM Influenza PGD v01.00 (National Community Pharmacy Advanced Service).	21 July 2016
V03.00	New Pharmacy Influenza Vaccination PGD for the 2017/2018 season to replace Pharmacy Influenza PGD v02.00. Amendments include: <ul style="list-style-type: none"> • addition of morbidly obese individuals to the inclusion criteria and deletion of related text in the additional information section • exclusion of people who have received a dose of influenza vaccine for the current season • statement that patients should be reassured that the inactivated vaccine cannot cause influenza but vaccine will not provide protection for about 14 days and does not protect against other respiratory viruses that often circulate during the flu season • minor rewording for clarity 	11 July 2017
V04.00	Pharmacy Influenza Vaccination PGD amended to include immunisation of health and social care staff, employed by a registered residential care/nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable patients/clients who are at increased risk from exposure to influenza.	01 November 2017
V05.00	Pharmacy Influenza Vaccination PGD amended to: <ul style="list-style-type: none"> • refer to updated National Minimum Standards and Core Curriculum for Immunisation Training • include vaccines available for 2018/19 season, including the adjuvanted trivalent influenza vaccine Flud[®] and related information regarding this product • include a table of recommended vaccine choice • provide further guidance on route of administration for individuals with bleeding disorders or on anticoagulants • refer to vaccine incident guidelines in off-label and storage sections • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	10 August 2018

1. PGD Development

This PGD has been developed by the following health professionals on behalf of PHE:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		10/08/2018
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		10/08/2018
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		10/08/2018

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Alison Hemsworth	Assistant Head of Primary Care Policy (Pharmacy and Dispensing Doctors), Strategy and Innovation Directorate, NHS England
Jane Horsfall	Programme Lead, Pharmacy Contracts & Projects, Strategy and Innovation Directorate, NHS England
Jacqueline Lamberty	Lead Pharmacist Medicines Management Service, Public Health England
Jill Loader	Head of Pharmacy Commissioning, NHS England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England, NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Richard Pebody	Consultant Medical Epidemiologist, Immunisation and Countermeasures, Public Health England
Gul Root	National lead pharmacy public health, Public Health England and Principal Pharmaceutical Officer, Department of Health
Tushar Shah	Pharmacy Advisor, NHS England London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East

Sharon Webb	Programme Manager - IDPS , NHS Screening Programmes, Public Health England (Midwife)
Helen Wilkinson	Principal Pharmacist Bristol, North Somerset & South Gloucestershire Clinical Commissioning Group.

2. Organisational Authorisations

NHS England accepts governance responsibility for this PGD. Any community pharmacy contractor providing the advanced service must work strictly within the terms of this PGD and The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions, covering the advanced service, published in the Drug Tariff. Any deviation will be treated as a serious contractual breach.

NHS England authorises this PGD for use by community pharmacy contractors delivering the community pharmacy seasonal influenza vaccination advanced service.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Director of Primary Care Commissioning	David Geddes GMC no. 3253722		20/08/2018

Enquiries regarding the use of this PGD may be directed to:

ENGLAND.communitypharmacy@nhs.net

The community pharmacy contractor must complete the practitioner authorisation sheet included at the end of this PGD (see [Section 7](#)).

3. Characteristics of Staff

Qualifications and professional registration	Pharmacists registered with the General Pharmaceutical Council (GPhC).
Additional requirements	<p>Pharmacists:</p> <ul style="list-style-type: none"> • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it (ie by completion of Section 7) • must have undertaken appropriate training for working under PGDs for supply/administration of medicines as required by the community pharmacy seasonal influenza vaccination advanced service specification, the declaration of competence for vaccination services and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs) • must be familiar with the vaccine products and alert to changes in their Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (“The Green Book”), and the national immunisation programme • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the “cold chain” as outlined in the CPPE declaration of competence for vaccination services • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources. <p>THE PHARMACIST MUST BE AUTHORISED BY NAME, UNDER THE CURRENT NHS ENGLAND AUTHORISED VERSION OF THIS PGD BEFORE WORKING UNDER ITS AUTHORITY.</p>
Continued training requirements	<p>Pharmacists should ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD).</p> <p>Pharmacists should be constantly alert to any subsequent recommendations from PHE and/or NHS England and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed. However, if updated recommendations mean that to vaccinate the individual would be outside the scope of this PGD, the individual should be referred to their GP for vaccination.</p>

4. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<p>Inactivated influenza vaccine is indicated for the active immunisation of adults for the prevention of influenza infection, in accordance with the community pharmacy seasonal influenza vaccination advanced service, the national immunisation programme and recommendations given in Chapter 19 of the Immunisation Against Infectious Disease: “The Green Book”, the annual flu letter and subsequent correspondence/publications from PHE and/or NHS England.</p>
<p>Criteria for inclusion</p>	<p>In 2018/19, flu vaccinations may be offered at NHS expense to the following groups under the community pharmacy seasonal influenza vaccination advanced service:</p> <ul style="list-style-type: none"> • people aged 65 years or over (including those becoming age 65 years by 31 March 2019) • adults aged from 18 years to less than 65 years of age in a clinical risk group (see Appendix A) such as: <ul style="list-style-type: none"> ○ 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 three, four or five ○ chronic liver disease ○ chronic neurological disease, such as Parkinson’s disease or motor neurone disease, or learning disability ○ diabetes ○ asplenia or splenic dysfunction ○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment) ○ morbidly obese (defined as BMI of 40 and above) ○ pregnant women aged 18 years and over (including those women who become pregnant during the flu season) • adults (aged 18 years and over) living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions or university halls of residence • adults (aged 18 years and over) who are in receipt of a carer’s allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill • adult household contacts (aged 18 years and over) of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and therefore for whom continuing close contact is unavoidable • health and social care staff (aged 18 years and over), employed by a registered residential care/nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable¹ patients/clients who are at increased risk from exposure to influenza • health and care staff (aged 18 years and over), employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable¹ patients/clients who are at increased risk from exposure to influenza

¹ Vulnerable means those patients/clients in a clinical risk group for flu or who are aged 65 years and over

<p>Criteria for exclusion²</p>	<p>Individuals for whom no valid consent has been received (for further information on consent see DH Reference guide to consent for examination or treatment).</p> <p>People who:</p> <ul style="list-style-type: none"> • are less than 18 years of age • have had a confirmed anaphylactic reaction to a previous dose of the vaccine • have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process³ (other than ovalbumin – see Cautions) • have had a severe anaphylactic reaction to egg which has previously required intensive care • have received a dose of influenza vaccine for the current season <p>Temporary Exclusion</p> <p>Administration of inactivated influenza vaccine should be postponed for individuals suffering from acute severe febrile illness. The presence of a minor infection is not a contraindication for immunisation.</p>
<p>Cautions including any relevant action to be taken</p>	<p>Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration).</p> <p>With the exception of those individuals with severe anaphylaxis to egg which has previously required intensive care (see Criteria for exclusion), individuals 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 for 0.5 ml dose). For details of the influenza vaccines available for the 2018/19 season and their ovalbumin content see Influenza vaccine: ovalbumin content.</p> <p>Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p>
<p>Action to be taken if the patient is excluded</p> <p>Continued over page</p>	<p>The risk to the individual of not being immunised should be taken into account. The indications for flu vaccination are not exhaustive, and pharmacists should take into account the risk of flu exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from flu itself and refer individuals to their GP for immunisation where appropriate.</p> <p>All individuals under 18 years of age who are in a clinical risk group (including those who are pregnant) should be referred to their GP for immunisation.</p> <p>Egg allergy</p> <p>Individuals with severe anaphylaxis to egg which has previously</p>

² Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for administration of vaccine will be required

³ Residues from the manufacturing process may include barium sulphate, cetyltrimethylammonium bromide (CTAB), formaldehyde, gentamicin, kanamycin, neomycin, octoxinol-9, polymyxin, polysorbate 80, sodium deoxycholate. Check the vaccine products SPC for details.

<p>Action to be taken if the patient is excluded (continued)</p>	<p>required intensive care should be referred to their GP. Document reason for exclusion and any action taken in patient's clinical records.</p> <p>Temporary exclusion In case of postponement due to acute illness, advise when the individual can return for vaccination.</p>
<p>Action to be taken if the patient or carer declines treatment</p>	<p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and decision reached and inform patient's GP as appropriate.</p>
<p>Arrangements for referral for medical advice</p>	<p>Refer to individual's GP.</p>

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5. Description of Treatment

<p>Name, strength & formulation of drug</p>	<p>Inactivated influenza vaccine suspension in a pre-filled syringe, ie:</p> <ul style="list-style-type: none"> • inactivated quadrivalent influenza vaccine (QIV) • inactivated adjuvanted trivalent influenza vaccine (aTIV) • inactivated trivalent influenza vaccine (TIV) <p>A list of the influenza vaccines available in the UK was published in the annual flu letter for England and subsequent updates can be found in Vaccine Update.</p> <p>Recommended vaccine choice</p> <table border="1" data-bbox="523 577 1423 1317"> <thead> <tr> <th data-bbox="523 577 724 645">Age</th> <th data-bbox="724 577 1423 645">Recommended influenza vaccine</th> </tr> </thead> <tbody> <tr> <td data-bbox="523 645 724 797">18 years to under 65 years</td> <td data-bbox="724 645 1423 797">Offer QIV. Note: LAIV (Fluenz Tetra®▼) and aTIV (Fluad®) are not licensed in this age group.</td> </tr> <tr> <td data-bbox="523 797 724 1317">65 years and over (including 64 year olds turning 65 years old by 31 March 2019)</td> <td data-bbox="724 797 1423 1317">The aTIV (Fluad®) is recommended as the adjuvanted vaccine is more effective than non-adjuvanted vaccine in this population. The use of the aTIV (Fluad®) should be a priority for those aged 75 years and over, given that the non-adjuvanted vaccine has shown no significant effectiveness in this group over recent seasons. QIV should be offered as a second line option to aTIV if aTIV is unobtainable (see Additional Information) or otherwise unsuitable (eg due to egg allergy). Note: LAIV (Fluenz Tetra®▼) is not licensed in this age group.</td> </tr> </tbody> </table> <p>Note: Non-adjuvanted trivalent influenza vaccine (TIV) is not one of the recommended vaccines for 2018/19 but may be administered where the recommended vaccine choices as detailed above are unobtainable (see Additional Information).</p>	Age	Recommended influenza vaccine	18 years to under 65 years	Offer QIV. Note: LAIV (Fluenz Tetra®▼) and aTIV (Fluad®) are not licensed in this age group.	65 years and over (including 64 year olds turning 65 years old by 31 March 2019)	The aTIV (Fluad®) is recommended as the adjuvanted vaccine is more effective than non-adjuvanted vaccine in this population. The use of the aTIV (Fluad®) should be a priority for those aged 75 years and over, given that the non-adjuvanted vaccine has shown no significant effectiveness in this group over recent seasons. QIV should be offered as a second line option to aTIV if aTIV is unobtainable (see Additional Information) or otherwise unsuitable (eg due to egg allergy). Note: LAIV (Fluenz Tetra®▼) is not licensed in this age group.
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<p>Legal category</p>	<p>Prescription only medicine (POM).</p>						
<p>Black triangle▼</p>	<p>QIVs are black triangle (including GSK's Fluarix® Tetra▼ and MASTA, Mylan (BGP Products) and Sanofi Pasteur supplied QIV).</p>						
<p>Off-label use</p> <p>Continued over page</p>	<p>Fluad® (aTIV) is licensed for administration to individuals aged 65 years and over. It may be administered under this PGD to 64 year olds turning 65 years of age by 31 March 2019 in accordance with the recommendations for the national influenza immunisation programme for 2018/19.</p> <p>Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p>						

<p>Off-label use (continued)</p>	<p>Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p> <p>Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this PGD, unless permitted off-label administration is detailed above. Refer to products' SPCs at www.medicines.org.uk and Appendix F of the annual flu letter for more information.</p>
<p>Route / method of administration</p>	<p>Administer by intramuscular injection, preferably into the deltoid region of the upper arm.</p> <p>Due to the presence of adjuvant (MF59C), Flud[®] should be administered intramuscularly using a 25mm needle.</p> <p>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.</p> <p>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/carer should be informed about the risk of haematoma from the injection.</p> <p>Influenza vaccines licensed for intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. Subcutaneous administration is covered by this PGD where the pharmacist is trained and competent in administration via the subcutaneous route. Note: Fluarix[®] Tetra ▼ and Flud[®] are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD.</p> <p>When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations.</p> <p>The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. If Flud[®] needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs.</p> <p>Shake vaccine before administration.</p> <p>Inspect visually prior to administration and ensure appearance is consistent with the description in the SPC for the vaccine being</p>

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Route / method of administration (continued)	administered. The SPC for each vaccine provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk
Dose and frequency of administration	Single 0.5ml dose to be administered for the current annual flu season (1 September 2018 to 31 March 2019).
Duration of treatment	Single 0.5ml dose for the current annual flu season.
Quantity to be supplied / administered	Single dose of 0.5ml per administration.
Supplies	Providers should order influenza vaccines for adults from the influenza vaccine manufacturers or pharmaceutical wholesalers as in previous years, with due consideration of the recommended vaccine choice .
Storage	Store between +2°C to +8°C. Do not freeze. Store in original packaging in order to protect from light. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance .
Disposal	Equipment used for immunisation, including discharged vaccines in a syringe, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to guidance in the technical memorandum 07-01 : Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment but it is important to still immunise this group. Inactivated influenza vaccination may be given at the same time as other vaccines (see Route / method of administration). A detailed list of drug interactions associated with inactivated influenza vaccine is available in the SPC for each vaccine, which are available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	Pain, swelling or redness at the injection site, low grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms after intramuscular vaccination. A small painless nodule (induration) may also form at the injection site. These symptoms usually disappear within one to two days without treatment. Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur. A higher incidence of mild post-immunisation reactions has been reported with aTIV compared to non-adjuvanted influenza vaccines. The frequency of injection site pain and systemic reactions may be higher in individuals vaccinated concomitantly with inactivated influenza vaccine and pneumococcal polysaccharide vaccine (PPV23) compared to vaccination with influenza vaccine alone and similar to
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Identification & management of adverse reactions (continued)	<p>that observed with PPV23 vaccination alone. Influenza vaccine and PPV23 may be administered at the same visit.</p> <p>A detailed list of adverse reactions associated with inactivated influenza vaccine is available in the SPC for each vaccine, which are available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Reporting procedure of adverse reactions	<p>Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk</p> <p>QIVs are black triangle (including GSK's Fluarix® Tetra▼ and MASTA, Mylan (BGP Products) and Sanofi Pasteur supplied QIV). Therefore, any suspected adverse reactions should be reported via the Yellow Card Scheme.</p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p>
Written information to be given to patient or carer	<p>Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p>
Patient advice / follow up treatment	<p>Individuals should be advised regarding adverse reactions to vaccination and reassured that the inactivated vaccine cannot cause influenza. However the vaccine will not provide protection for about 14 days and does not protect against other respiratory viruses that often circulate during the flu season.</p> <p>Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Therefore, consideration should be given to the vaccination of household contacts of immunocompromised individuals.</p> <p>Inform the individual/carer of possible side effects and their management.</p> <p>The individuals/carer should be advised when and where to seek appropriate advice in the event of an adverse reaction.</p> <p>Advise the individual/carer when a subsequent vaccine dose is due ie single immunisation for each annual influenza season.</p> <p>When administration is postponed, advise the individual/carer when to return for vaccination.</p>
Special considerations / additional information Continued over page	<p>The pharmacist should have immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.</p> <p>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.</p> <p>The recommended vaccine in those aged 65 years and over is aTIV. QIV should not be offered to those aged 65 years and over, other than in exceptional circumstances. In the event that aTIV is not available, and is highly unlikely to become available, QIV may be offered as a second line option. Before offering the second line option, however, individuals should be sign-posted to other providers to access the recommended vaccine, as appropriate.</p>

<p>Special considerations / additional information (continued)</p>	<p>Non-adjuvanted trivalent influenza vaccine (TIV) is not one of the recommended vaccines for 2018/19. For those aged under 65 years, if QIV is not available, and is highly unlikely to become available, TIV may be offered as a second line option. For those aged 65 years and over, if neither QIV nor aTIV are available, and are highly unlikely to become available, TIV may be administered in exceptional circumstances. In both situations, individuals should be sign-posted to other providers to access the recommended vaccine, as appropriate.</p> <p>If offering QIV to individuals not recommended to have it, or if offering non-adjuvanted TIV to any individual, when gaining consent for immunisation, pharmacists should ensure they inform the individual the vaccine is not one nationally recommended for them. Pharmacists should ensure they explain to the individual the possible lower efficacy of the vaccine being offered to them, why it is being offered instead of the recommended vaccine and why it may still offer protection against seasonal flu, or attenuate the progression of the infection should they get it. The discussion should be documented in the individuals' records.</p> <p>Individuals should consent to information sharing with their GP practice as part of the consent process for accessing this service. Individuals who are not registered with a GP practice may be vaccinated at the professional discretion of the pharmacist, weighing up risks and benefits for the individual. They should be encouraged to register with a GP as appropriate to their circumstances or be referred to appropriate alternative medical services as required.</p>
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • that valid informed consent was given • name of individual, address, date of birth and GP practice with whom the individual is registered (or record where an individual is not registered with a GP and that appropriate advice has been given) • eligible/clinical risk group indication for immunisation • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if not vaccinated • details of any adverse drug reactions and actions taken • supplied via PGD <p>Records should be signed and dated or if using electronic records, the immuniser's account should be password protected such as to provide an electronic signature to the vaccination record.</p> <p>All records should be clear, legible, contemporaneous and in line with the community pharmacy seasonal influenza immunisation advanced service specification.</p> <p>As a wide variety of influenza vaccines are available on the UK market each year, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records.</p>
<p>Continued over page</p>	<p>It is important that vaccinations given at community pharmacies are</p>

Records (continued)	recorded in a timely manner. A record of the vaccination should be returned to the individual's GP practice (as specified in the service specification) to allow clinical follow up and to avoid duplicate vaccination. Records of all individuals receiving treatment under this PGD should also be kept for audit purposes and post payment verification.
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6. Key References

Key references	Inactivated influenza vaccination <ul style="list-style-type: none">• Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 15 August 2018 https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19• Collection: Annual Flu Programme https://www.gov.uk/government/collections/annual-flu-programme• The national flu immunisation programme 2018 to 2019: supporting letter. Published 26 March 2018 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan• Influenza vaccine ovalbumin content https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content• Declaration of competence for vaccination services https://www.cppe.ac.uk/services/declaration-of-competence• Summary of Product Characteristics www.medicines.org.uk General <ul style="list-style-type: none">• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. https://www.nice.org.uk/guidance/mpg2/resources• PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation• PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors• Reference guide to consent for examination or treatment, Department of Health, published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition
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7. Practitioner authorisation sheet

Pharmacy Influenza Vaccination PGD v05.00 Valid from: 01/09/2018 Expiry: 31/03/2019

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

Authorising manager

I confirm that the pharmacists named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **INSERT NAME OF ORGANISATION** for the above named pharmacists who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent pharmacist additions post managerial authorisation.

A copy of this PGD with completed practitioner authorisation sheet should be retained and available at the pharmacy premises as a record of those pharmacists authorised to work under this PGD.

APPENDIX A

Clinical risk groups who should receive the influenza immunisation

Influenza vaccine should be offered to people* in the clinical risk categories set out below.

Clinical risk category	Examples (this list is not exhaustive and decisions should be based on clinical judgement)
Chronic respiratory disease	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children* who have previously been admitted to hospital for lower respiratory tract disease.
Chronic heart disease	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
Chronic kidney disease	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease	Cirrhosis, biliary atresia, chronic hepatitis.
Chronic neurological disease	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (eg polio syndrome sufferers). Clinicians should offer immunisation, based on individual assessment, to clinically vulnerable individuals including those with cerebral palsy, learning disabilities, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability.
Diabetes	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes.
Immunosuppression	Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (eg IRAK-4, NEMO, complement disorder). Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day. It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immunocompromised patients may have a suboptimal immunological response to the vaccine.
Asplenia or dysfunction of the spleen	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Morbidly obese	Adults with a Body Mass Index ≥ 40 kg/m ² .
Pregnant women	Pregnant women at any stage of pregnancy (first, second or third trimesters).

*Note: People under 18 years of age should be referred to an alternative service for vaccination.