Public Health England

NHS publishing approval reference: 0101

Inactivated influenza vaccine Patient Group Direction (PGD)

This PGD is for the 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:	v07.00
Valid from:	1 September 2020
Expiry date:	31 March 2021

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

NHS England and NHS Improvement 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 and NHS Improvement 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 and NHS Improvement as the commissioner and the community pharmacy contractor as the service provider. The final authorised copy of this PGD should be kept by NHS England and NHS Improvement and community pharmacy contractors for 8 years after the PGD expires.

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/publication/community-pharmacy-seasonal-influenza-vaccine-service/

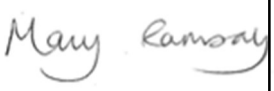
Any enquiries regarding this PGD should be addressed to:
ENGLAND.communitypharmacy@nhs.net

Change History

Version number	Change details	Date
V01.00	New PHE PGD template	18 August 2015
V01.00 (National Community Pharmacy Advanced Service)	See earlier version of this PGD for change details.	03 September 2015
V02.00	See earlier version of this PGD for change details.	21 July 2016
V03.00	See earlier version of this PGD for change details.	11 July 2017
V04.00	See earlier version of this PGD for change details.	01 November 2017
V05.00	See earlier version of this PGD for change details.	10 August 2018
V06.00	Pharmacy Influenza Vaccination PGD amended to: • include vaccines for the 2019/20 season, including cell-based quadrivalent influenza vaccine (QIVc) • update cautions for egg allergy and include use of QIVc which is egg free for individuals with a severe anaphylaxis to egg which has previously required intensive care	08 May 2019
V07.00	Pharmacy Influenza Vaccination PGD amended to: • add paragraph on document retention to the front page • include household contacts of those on the NHS Shielded Patient List, health and social care workers employed through Direct Payments or Personal Health Budgets, and potential in season extension of the programme to individuals from 50 years of age • update the table of recommended inactivated influenza vaccines for the 2020/21 season • remove reference to Fluad® brand which will not be supplied to UK this season and remove black triangle from Fluarix® Tetra • remove reference to barium sulphate which is no longer listed in the adjuvanted trivalent influenza influenza vaccine SPC as a residue of the manufacturing process • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	24 August 2020

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		25/08/2020
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		25/08/2020
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		25/08/2020

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
Nicholas Aigbogun	Consultant in Communicable Disease Control, Public Health England
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jane Horsfall	Senior Policy Manager, Community Pharmacy, Strategy and Innovation Directorate, NHS England and NHS Improvement
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Management Service, Public Health England
Jill Loader	Deputy Director, Pharmacy Commissioning, NHS England and NHS Improvement
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 and NHS Improvement (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Co-ordinator, Public Health England / NHS England and NHS Improvement (Central Midlands)
Gul Root	Principal Pharmaceutical Officer, Department of Health & Social Care and National lead pharmacy public health, Public Health England
Vanessa Saliba	Consultant Epidemiologist, Immunisation and Countermeasures, Public Health England
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)
Sharon Webb	Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England

2. Organisational Authorisations

NHS England and NHS Improvement 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 and NHS Improvement 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**
Deputy Medical Director for Primary Care, NHS England and NHS Improvement	Dr Raj Patel		26/08/20

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	Pharmacists: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it (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. For further information on immunisation training during the COVID-19 pandemic see Guidance on immunisation training during the COVID-19 pandemic. • 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 seasonal influenza 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. **The pharmacist must be authorised by name, under the current NHS England and NHS Improvement authorised version of this PGD before working under its authority.**
Continued training requirements	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). Pharmacists should be constantly alert to any subsequent recommendations from PHE and/or NHS England and NHS Improvement, and other sources of medicines information. 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.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	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', annual flu letters and subsequent correspondence/publications from PHE and/or NHS England and NHS Improvement.

Criteria for inclusion
 	
Continued over page
Criteria for inclusion
	In 2020/21, influenza vaccination may be offered at NHS expense to the following groups under the community pharmacy seasonal influenza vaccination advanced service:
	• people aged 65 years or over[1]
	• adults aged from 18 years to less than 65 years of age in a clinical risk group (see Appendix A) such as:
	  ○ 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,
	  ○ 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 40kg/m^2 and above)
	  ○ pregnant women (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 those on the NHS Shielded Patient List, or of immunocompromised individuals, specifically individuals who expect to share living accommodation with a shielded patient 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 vulnerable[2] 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

[1] including those becoming age 65 years by 31 March 2021
[2] Vulnerable means those patients/clients in a clinical risk group for flu or who are aged 65 years and over

continued	the care of vulnerable[2] patients/clients who are at increased risk from exposure to influenza • health and social care workers employed through Direct Payments (personal budgets) and/or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to patients and service users. Additionally, in 2020/21, subject to sufficient inactivated influenza vaccine supplies being available nationally, the offer of inactivated influenza vaccine may be extended to people aged: • 64 to 65 years • 63 to 64 years • 62 to 63 years • 61 to 62 years • 60 to 61 years • 59 to 60 years • 58 to 59 years • 57 to 58 years • 56 to 57 years • 55 to 56 years • 54 to 55 years • 53 to 54 years • 52 to 53 years • 51 to 52 years • 50 to 51 years The date from which individuals in these age cohorts may be vaccinated will be formally announced later in the flu season. A copy of this announcement will be made available at: https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan. An announcement may relate to just one year group or more than one year group. Confirmation that the use of this PGD may be extended to a specified year group or groups will be provided with authorisation from the national PGD signatories and will then be published, together with the start date for the extension, by NHS England and NHS Improvement at: www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service and communicated to community pharmacies via NHS mail.
Criteria for exclusion[3]	Individuals for whom no valid consent has been received (for further information on consent see Reference guide to consent for examination or treatment). People who: • 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 process[5] (other than ovalbumin – see Cautions)

[3] 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

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

Continued over page **Criteria for exclusion**[4] (continued)	• have received a complete dose of the recommended influenza vaccine for the current season • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken	Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). Individuals with a severe anaphylaxis to egg which has previously required intensive care can be immunised in any setting using an egg-free vaccine, for instance QIVc. Individuals with less severe egg allergy can be immunised in any setting using an egg-free vaccine or 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 2020/21 season and their ovalbumin content see Influenza vaccines: 2020 to 2021 flu season. 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.
Action to be taken if the patient is excluded	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. 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 or an appropriate local NHS service provider for immunisation. In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Document the reason for exclusion and any action taken in the individual's clinical records.
Action to be taken if the patient or carer declines treatment	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.
Arrangements for referral for medical advice	Refer to individual's GP.

[4] 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

5. Description of Treatment

<table>
<tr><td>Name, strength & formulation of drug</td><td>Inactivated influenza vaccine suspension in a pre-filled syringe including:
adjuvanted trivalent influenza vaccine (aTIV)
cell-based quadrivalent influenza vaccine (QIVc)
egg-grown quadrivalent influenza vaccine (QIVe)
Note: This PGD does not include high-dose trivalent influenza vaccine (TIV-HD) or standard dose non-adjuvanted trivalent influenza vaccine (TIVe) as these vaccines are not eligible for re-imbursement under the NHS influenza vaccination programme in 2020/21.

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.

Inactivated influenza vaccine selection<table><tr><th>Age</th><th>Recommended influenza vaccine for adults</th></tr><tr><td>18 years to under 65 years</td><td>Offer QIVc or QIVe (as an alternative to QIVc).</td></tr><tr><td>65 years and over[1]</td><td>Offer aTIV (see Off-label use section).

QIVc is suitable for use in this age group if aTIV is not available or is not suitable due to egg allergy.</td></tr></table></td></tr>
<tr><td>Legal category</td><td>Prescription only medicine (POM).</td></tr>
<tr><td>Black triangle▼</td><td>QIVc and QIVe products, with the exception of Fluarix® Tetra, are black triangle.

This information was accurate at the time of writing. See product SPCs at www.medicines.org.uk for indication of current black triangle status.</td></tr>
<tr><td>Off-label use</td><td>The 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 2021 in accordance with the recommendations for the national influenza immunisation programme for 2020/21.

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.

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.

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 the table of 'Influenza vaccines: 2020 to 2021 flu season' for more information.</td></tr>
</table>

Route / method of administration	Administer by intramuscular injection, preferably into the deltoid region of the upper arm. 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 such as 25 gauge) 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 such as 25 gauge) 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. 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, Flucelvax® Tetra▼ and aTIV are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD. 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. 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 aTIV needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs. Shake vaccine before administration. Inspect visually prior to administration and ensure appearance is consistent with the description in the SPC for the vaccine being 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 2020 to 31 March 2021).
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. This season, to support the expanded flu programme and expected increased demand for flu vaccine across all cohorts, the Department of Health and Social Care (DHSC) has procured additional national supply of inactivated influenza vaccines and will issue guidance in September on how this can be accessed.
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 1 to 2 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 that observed with PPV23 vaccination alone. Influenza vaccine and PPV23 may be administered on the same day or at any interval from each other. 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

Reporting procedure of adverse reactions	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 QIVc and QIVe, with the exception of Fluarix® Tetra, are black triangle. Therefore, any suspected adverse reactions to these products 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.
Written information to be given to patient or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Patient advice / follow up treatment	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. 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. Inform the individual/carer of possible side effects and their management. The individual/carer should be advised when and where to seek appropriate advice in the event of an adverse reaction. In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed. Advise the individual/carer when a subsequent vaccine dose is due, such as a single immunisation for each annual influenza season. If the individual is eligible for PPV23 on the NHS and has not received it, pharmacists should signpost them to their GP or an appropriate provider to receive the vaccine on the NHS.
Special considerations / additional information Continued over page	Services should be provided following current infection prevention and control guidance and recommendations for appropriate COVID-19 personal protective equipment (PPE) (see https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control). The pharmacist should have immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination. 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. The NHS Shielded Patient List may be subject to revision. The household contacts of those on the NHS Shielded Patient List current at the time of immunisation are eligible. Individuals who are not registered with a GP practice may be vaccinated at the professional discretion of the pharmacist, weighing

Special considerations / additional information continued	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.
Records	Record: • 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 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. All records should be clear, legible, contemporaneous and in line with the community pharmacy seasonal influenza immunisation advanced service specification. 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. It is important that vaccinations administered are 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. For pregnant women, also record immunisation in the hand held maternity record (if available). Records of all individuals receiving treatment under this PGD should also be kept for audit purposes and post payment verification.

6. Key References

Key references	**Inactivated influenza vaccination** • Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 23 April 2019 https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19 • Collection: Annual Flu Programme. Updated 7 August 2020 https://www.gov.uk/government/collections/annual-flu-programme • Community Pharmacy Seasonal Influenza Vaccine Service https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service/ • The national flu immunisation programme 2020 to 2021: supporting letter. Published 14 May 2020 and update published 5 August 2020 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan • Coronavirus (Covid-19): Shielded patients list. NHS Digital. Updated 6 July 2020 https://digital.nhs.uk/coronavirus/shielded-patient-list • Influenza vaccines: 2020 to 2021 flu season 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** • 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. Updated March 2017 https://www.nice.org.uk/guidance/mpg2/resources • PHE Guidance on immunisation training during the COVID-19 pandemic. 26 June 2020. https://www.gov.uk/government/publications/immunisation-training-guidance-during-the-covid-19-pandemic/guidance-on-immunisation-training-during-the-covid-19-pandemic • 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

Continued over page

Key references continued	• Reference guide to consent for examination or treatment, Department of Health and Social Care. Published 4 August 2009 https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

7. Practitioner authorisation sheet

Pharmacy Influenza Vaccination PGD v07.00 Valid from: 01/09/2020 Expiry: 31/03/2021

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 (e.g. 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 (e.g. 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.