UK Health Security Agency

NHS England

NHS publishing approval reference: PRN01418

Community Pharmacy 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 practitioners delivering the community pharmacy seasonal influenza vaccination advanced service.

Reference:	Community Pharmacy Influenza Vaccination PGD
Version no:	v13.00
Valid from:	1 September 2024
Expiry date:	1 April 2025

The UK Health Security Agency (UKHSA) has developed this PGD for authorisation by NHS England (NHSE) to facilitate delivery of the national immunisation programme in England.

NHSE 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 NHSE only. Section 7 is to be completed by the community pharmacy contractor providing the advanced service.

Operation of this PGD is the responsibility of NHSE as the commissioner and the community pharmacy contractor as the service provider. The final authorised copy of this PGD should be kept by NHSE and community pharmacy contractors for 8 years after the PGD expires.

A practitioner 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 countersignature.

Providers must check that they are using the current version of this 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: NHS England » Community Pharmacy Seasonal Influenza Vaccine Service

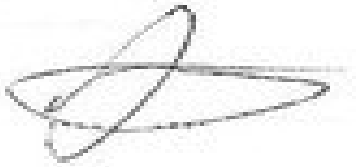
Any enquiries regarding this PGD should be addressed to:
ENGLAND.communitypharmacy@nhs.net

Change history

Version number	Change details	Date
v1.00 to v7.00	See earlier version of this PGD for change details.	18 August 2015 to 24 August 2020
v8.00	Pharmacy Influenza Vaccination PGD amended to: • include registered professionals who can legally supply and administer under a PGD • include eligible cohorts for the 2021 to 2022 season • include the inactivated influenza vaccines for the 2021 to 2022 season • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	27 July 2021
v9.00	Pharmacy Influenza Vaccination PGD amended to: • include primary care contractors (primary medical services, pharmaceutical services, primary dental services or general ophthalmic services) and their frontline staff, including locums • mention consent or 'best-interests' decision in accordance with the Mental Capacity Act 2005 • update additional information and drug interactions sections • update for change of organisation from PHE to UKHSA • web addresses hyperlinked into body text for clarity and consistency with other UKHSA PGDs	12 October 2021
v10.00	Pharmacy Influenza Vaccination PGD amended to: • include only eligible cohorts for the 2022 to 2023 influenza season • include the inactivated influenza vaccines for the 2022 to 2023 season • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs	28 June 2022
v11.00	Pharmacy Influenza Vaccination PGD amended to remove declaration of competence for vaccination services from additional requirements under staff characteristics	5 September 2022
v12.00	Community Pharmacy Influenza Vaccination PGD amended to: • include eligible cohorts for the 2023 to 2024 season • include the recommended influenza vaccines for the 2023 to 2024 season • include updated advice on co-administration of aQIV with Shingrix® (shingles) vaccine	17 July 2023
v13.00	Community Pharmacy Influenza Vaccination amended to: • update eligibility criteria for the 2024 to 2025 season • advise earlier immunisation of pregnant women from 1 September; remaining cohorts to commence in October (precise date TBC by NHS England) • incorporate amendments to the flu letter from 12 June 2024, including choice of vaccines recommended by age; separation of the 18 to 64 year cohort into 18 to 59 years and 60 to 64 years to reflect QIV-HD licensing • include pharmacy technicians as an additional professional group, as outlined in the relevant Amendments to HMR 2024 • include minor rewording, layout and formatting changes for consistency with other UKHSA PGDs	20 June 2024

1. PGD development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead author)	Christina Wilson Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Division, UKHSA		14 June 2024
Doctor	Jamie Lopez-Bernal Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 June 2024
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 June 2024

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Committee.

In addition to the signatories above, the Working Group included:

Name	Designation
David Onuoha	Service Development Manager, Community Pharmacy England

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Specialist Pharmacist, Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Primary Care Based, Southbourne Surgery
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health ProtectionTeam, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London

2. Organisational authorisations

NHSE accepts responsibility for governance of 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.

NHSE 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 Vaccination, NHSE	Caroline Temmink		21 June 2024

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	**All practitioners should only administer vaccinations where it is within their scope of clinical practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below.** Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council
Additional requirements	Additionally, practitioners: • 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 and administration of medicines as required by the community pharmacy advanced service specification: seasonal influenza vaccination • 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 have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training. For further information see Flu immunisation training recommendations • 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 • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources **The practitioner must be authorised by name, under the current NHSE authorised version of this PGD before working under its authority.**

Continued training requirements	Practitioners 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). Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHSE 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 advanced service specification for seasonal influenza vaccination, the national immunisation programme and recommendations given in Chapter 19 of the Immunisation Against Infectious Disease: the Green Book, annual flu letter and subsequent correspondence and publications from UKHSA and NHSE.

Criteria for inclusion
 	
(continued over page)
	For the 2024 to 2025 influenza season, influenza vaccine should be offered at NHS expense to the following groups under the community pharmacy seasonal influenza vaccination advanced service:
	
	From 1 September 2024:
	• pregnant women aged 18 years and over (including those women who become pregnant during the influenza season)
	
	The precise date from which all other eligible individuals may be vaccinated will be communicated by NHSE; at the time of writing, this has been planned from October.
	
	Upon announcement of this date, this PGD may be used for vaccination of the following cohorts:
	• individuals aged 65 years or over (including those becoming age 65 years by 31 March 2025)
	• adults aged from 18 years to under 65 years of age in a clinical risk group category listed in Chapter 19 of the Green Book such as those with:
	  ○ chronic (long-term) respiratory disease, such as asthma (that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission), chronic obstructive pulmonary disease (COPD) or chronic bronchitis
	  ○ chronic heart disease and vascular disease
	  ○ 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 and adrenal insufficiency
	  ○ asplenia or dysfunction of the spleen
	  ○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as for cancer)
	  ○ morbidly obese adults with a BMI of 40kg/m^2 and above
	
	Adults aged from 18 years to under 65 years of age who are:
	• household contacts 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
	• 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, university halls of residence or boarding schools
	• carers: those who are in receipt of a carer's allowance, or who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill
	• frontline health and social care workers without employer-led occupational health schemes, employed:
	  ○ by a registered residential care or nursing home or registered domiciliary care provider, who are directly involved in the care of

Criteria for inclusion (continued)	vulnerable individuals who are at increased risk from exposure to influenza ○ by a voluntary managed hospice provider, who are directly involved in the care of vulnerable individuals who are at increased risk from exposure to influenza ○ through Direct Payments (personal budgets) or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to individuals ○ to deliver social care services and are in direct contact with those who are clinically vulnerable to flu, who receive care and support services from the social care provider
Criteria for exclusion[1]	Individuals who have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). For further information on consent, see Chapter 2 of the Green Book). Several sources are available to inform consent (see written information to be given to individual or carer section). Individuals 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[2] (other than ovalbumin – see cautions) • 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) **Note: This PGD covers NHS-commissioned services only. It may not be used for the provision of inactivated influenza vaccine via occupational health schemes or peer-to-peer immunisation. A written instruction should be used instead, for which the NHS Specialist Pharmacy Service produces a template.**
Cautions including any relevant action to be taken (continued over page)	Facilities for management of anaphylaxis should be available at all vaccination premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route and method of administration). Individuals with a severe anaphylaxis to egg which has previously required intensive care can be immunised in any setting using a suitable egg-free vaccine, for instance QIVc. Individuals with a less severe egg allergy can be immunised in any setting using a suitable egg-free vaccine, or an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to 0.06 micrograms per 0.5 ml dose). For details of the influenza vaccines available for the current season and their ovalbumin content, follow this link.

[1] 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.

[2] Residues from the manufacturing process may include beta-propiolactone, cetyltrimethylammonium bromide (CTAB), formaldehyde, gentamicin, hydrocortisone, kanamycin, neomycin, octoxinol-9, octylphenol ethoxylate, polysorbate 80, sodium deoxycholate. Check the vaccine's SPC for details.

Cautions including any relevant action to be taken (continued)	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 individual 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 the practitioner 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. Where appropriate, such individuals should be referred to their GP. Individuals under 18 years of age who are in a clinical risk group or otherwise eligible for influenza vaccination for the 2024 to 2025 season, should be referred to their GP or an appropriate local NHS service provider. In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Communicate and document the reason for exclusion and any action taken in the individual's clinical records.
Action to be taken if the individual 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. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. Advise the individual or 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 individual's GP as appropriate.
Arrangements for referral for medical advice	Refer to individual's GP.

5. Description of treatment

<table>
<tr><td>Name, strength and formulation of drug</td><td>Inactivated influenza vaccine suspension in a pre-filled syringe including:
adjuvanted quadrivalent influenza vaccine (aQIV)▼
cell-based quadrivalent influenza vaccine (QIVc)▼
egg-grown quadrivalent influenza vaccine (QIVe)
high-dose quadrivalent influenza vaccine (QIV-HD)▼
Some influenza vaccines are restricted for use in particular age groups. Refer to the vaccine's SPC, recommended vaccines and the off-label use section for further information.
Summary table of which inactivated influenza vaccines to offer (by age)
<table>
<tr><th>Age</th><th>Inactivated influenza vaccine to offer eligible individuals</th></tr>
<tr><td>18 years to 59 years (including in pregnancy)</td><td>Offer QIVc.
If QIVc is not available, offer QIVe[3].</td></tr>
<tr><td>60 to 64 years</td><td>Offer QIVc or QIV-HD.
If QIVc or QIV HD are not available, offer QIVe[4].</td></tr>
<tr><td>65 years and over, including those turning 65 by 31 March 2025</td><td>Offer aQIV or QIV-HD.
If aQIV or QIV-HD are not available, offer QIVc[5].
For those aged 64 who turn 65 years of age by 31 March 2025, aQIV may be offered off-label.
Note: QIVe is not recommended for those aged 65 years and over.</td></tr>
</table></td></tr>
<tr><td>Legal category</td><td>Prescription only medicine (POM).</td></tr>
<tr><td>Black triangle▼</td><td>QIVc, QIV-HD and aQIV vaccines are designated as black triangle products. Being newer vaccines, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for these products. All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme.
This information was accurate at the time of writing. See product SPCs, for indication of current black triangle status.</td></tr>
</table>

[3] QIVe should be offered only when every attempt to use QIVc has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

[4] QIVe should only be offered only when every attempt to use QIVc or QIV-HD has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

[5] QIVc should be offered only when every attempt to use aQIV or QIV-HD has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

Off-label use	Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual or carer the vaccine is being offered outside of product licence but in accordance with national guidance. aQIV is licensed for administration to individuals aged 65 years and over. It may be administered under this PGD to those aged 64 years and turning 65 years of age by 31 March 2025, in accordance with the recommendations for the national influenza immunisation programme for the 2024 to 2025 season (see the annual flu letter). Vaccines 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 Vaccine Incident Guidance. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD. Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this PGD, with the exception of off-label administration of aQIV as detailed above. Refer to product SPCs and Flu vaccines for the 2024 to 2025 season for more information.
Route and method of administration	Administer by intramuscular injection, preferably into the deltoid muscle of the upper arm. 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 or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. A fine needle (23 gauge or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. 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 (23 gauge or 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. The individual or carer should be informed about the risk of haematoma from the injection. Influenza vaccines licensed for both intramuscular and subcutaneous administration may alternatively be administered by the subcutaneous route. Note: QIVc and aQIV are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD. When co-administering with 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 aQIV needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs. Shake vaccine suspensions gently before administration. Visually inspect the vaccine prior to administration for foreign particulate matter,

(continued over page)

Route and method of administration (continued)	discolouration or other variation of expected appearance from that described in the vaccine's SPC. Discard the vaccine in accordance with local procedures, should any of these occur. Check product name, batch number and expiry date before administration. The SPC for each vaccine provides further guidance on administration.
Dose and frequency of administration	**QIVc, QIVe and aQIV:** Single 0.5ml dose to be administered for the current annual flu season (1 September 2024 to 31 March 2025). **QIV-HD only**: **Single 0.7ml dose** during the current annual flu season.
Duration of treatment	Single dose for the current annual flu season (1 September 2024 to 31 March 2025 as outlined in dose and frequency of administration above.
Quantity to be supplied and administered	**QIVc, QIVe and aQIV**: Single dose of 0.5ml per administration. **QIV-HD:** Single dose of 0.7ml per administration.
Supplies	Providers should order influenza vaccines for adults from the influenza vaccine manufacturers or pharmaceutical wholesalers as in previous years. Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3)
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, vaccines that have 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 Vaccine Incident Guidance.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste 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 local arrangements and NHSE guidance in (HTM 07-01): safe and sustainable management of healthcare waste.

Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Influenza vaccines can be co-administered with other vaccines including COVID-19 and shingles vaccines (see route and method of administration). Initially, a 7 day interval was recommended between Shingrix® (shingles) vaccine and adjuvanted influenza vaccine (aQIV) because the potential reactogenicity from 2 adjuvanted vaccines may reduce the tolerability in those being vaccinated. Interim data from a US study on co-administration of Shingrix® with adjuvanted seasonal influenza vaccine is reassuring. Therefore, an appointment for administration of the seasonal influenza vaccine can be an opportunity to also provide shingles vaccine (see Shingrix® PGD). Where aQIV is given with other vaccines, including other adjuvanted vaccines, the adverse effects of both vaccines may be additive and should be considered when informing the recipient. Individuals should also be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval. A detailed list of drug interactions is available in the SPC for each vaccine.
Identification and 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 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 adjuvanted 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.
Reporting procedure of adverse reactions	Healthcare professionals, individuals and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store. QIVc, QIV-HD and aQIV are black triangle vaccines. All suspected adverse reactions to these products should be reported via the Yellow Card reporting scheme, as these particular vaccines are newer to market. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed as appropriate.
Written information to be given to individual or carer (continued over page)	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Offer promotional material as appropriate: • the flu vaccination: who should have it and why (as updated for winter 2024 to 2025) • protect yourself from flu, have the flu vaccine: information for people with a learning disability leaflet

Written information to be given to individual or carer (continued)	For information leaflets in accessible formats and alternative languages, please visit Home-Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic Medicines Compendium.
Advice and 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 or carer of possible side effects and their management. The individual or carer should be advised when and where to seek appropriate advice in the event of an adverse reaction and encouraged to report this via the Yellow Card reporting scheme. 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 or carer when a subsequent vaccine dose is due, such as a single immunisation for each annual influenza season. If the individual is eligible for another vaccine on the NHS and has not received it, such as the COVID-19 vaccine, PPV23 or shingles vaccine, they should be signposted to their GP or an appropriate NHS provider.
Special considerations and additional information	The practitioner 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. Individuals who are not registered with a GP practice may be vaccinated at the professional discretion of the practitioner, 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. Individuals with learning disabilities may require reasonable adjustments to support vaccination (see Flu vaccinations: supporting people with learning disabilities). **Timing of doses** As outlined in the flu letter, vaccination of pregnant women should begin from 1 September, to ensure that as many newborn babies as possible are protected during the flu season. Vaccination of remaining cohorts should commence from October (precise date to be confirmed by NHSE). There may be a small number of other adults for whom delaying vaccination is not advised, for example individuals due to commence immunosuppressive treatment before the announced start date for vaccination. Clinicians should use clinical judgement to bring forward vaccination in such exemptions and when vaccine supply becomes available. A PSD should be used.

Records	The practitioner must ensure the following is recorded: • that valid informed consent was given • name of individual, address, date of birth and GP practice with whomthe individual is registered (or record where an individual is not registered with a GP and that appropriate advice has been given) • eligibility or 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 to append 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 and electronic 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 3 November 2023 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 • Community Pharmacy Advanced Service Specification: Seasonal Influenza https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service/ • JCVI advice on influenza vaccines for the 2024/ 2025 season, updated 25 August 2023 https://app.box.com/s/t5ockz9bb6xw6t2mrrzb144njplimfo0/file/1289995245447 • The national flu immunisation programme 2024 to 2025 letter, published 12 March 2024 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2024-to-2025/national-flu-immunisation-programme-2024-to-2025-letter • Statement of amendment to the annual flu letter for 2024 to 2025, published 12 June 2024 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2024-to-2025/statement-of-amendment-to-the-annual-flu-letter-for-2024-to-2025-12-june-2024 • All influenza vaccines marketed in the UK for the 2024 to 2025 season, updated 21 March 2024 https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk • Competency assessment tools for vaccination services https://www.cppe.ac.uk/services/declaration-of-competence • Flu immunisation training recommendations, updated 8 August 2023 https://www.gov.uk/government/publications/flu-immunisation-training-recommendations • Flu Vaccinations: Supporting people with learning disabilities, updated 25 September 2018 https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • Immunisation Against Infectious Disease: The Green Book, Chapter 2, updated 12 October 2023 https://www.gov.uk/government/publications/consent-the-green-book-chapter-2 • National Minimum Standards and Core Curriculum for Immunisation Training, published 7 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 27 March 2017 https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for healthprofessionals using patient group directions, updated 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources

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Key references (continued)	• UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • UK Statutory Instruments 2024, Number 729. The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024, published 29 May 2024 https://www.legislation.gov.uk/uksi/2024/729/introduction/made

7. Practitioner authorisation sheet

Community Pharmacy Influenza Vaccination PGD v13.00
Valid from: 1 September 2024 Expiry: 1 April 2025

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 practice 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 practitioners 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 practitioners 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 practitioner 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 practitioners authorised to work under this PGD.