Patient Group Direction (PGD) for the administration of

INACTIVATED INFLUENZA VACCINE TO ADULTS

By registered professionals who can legally supply and administer under a PGD to staff working for Durham County Council (DCC) accessing the DCC Staff Influenza Vaccination Service from Commissioned Community Pharmacies within County Durham

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

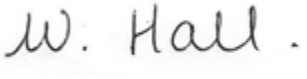
Direction Number: **DCC 2025/0001**

Valid from: 1st October 2025

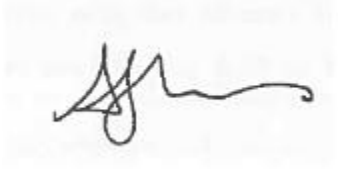
Expiry date: 31st March 2026

Change history

Version number	Change details	Date
V 2020/0001	New PGD template	July 2020
V 2021/0001	Pharmacy Influenza Vaccination PGD amended to: • include the recommended inactivated influenza vaccines for the 2021/22 season • remove the need for completion of a pharmacy flu voucher for vaccinations taking place at a pharmacy premises • alter the inclusion criteria based on age of staff to take account of the location of service delivery and eligibility for a NHS flu vaccination	April 2021
V 2022/0001	Pharmacy Influenza Vaccination PGD amended to: • include the recommended inactivated influenza vaccines for the 2022/23 season • reflect the eligibility for an NHS flu vaccination in 2022/23	July 2022
V 2023/0001	Pharmacy Influenza Vaccination PGD amended to: • include the recommended inactivated influenza vaccines for the 2023/24 season • reflect the eligibility for an NHS flu vaccination in 2023/24 • include the provision of flu vaccinations by registered nurses	June 2023
V 2024/0001	Pharmacy Influenza Vaccination PGD amended to: • include the recommended inactivated influenza vaccines for the 2024/25 season • reflect the eligibility for an NHS flu vaccination in 2024/25 • alter the inclusion criteria on age of staff to include those aged 65 years and above, taking into account of the location of service delivery • alter the provision of flu vaccinations to any registered professional who can legally supply and administer under a PGD	May 2024
V 2025/0001	Pharmacy Influenza Vaccination PGD amended to: • include the inactivated influenza vaccines for the 2025/26 season described in the annual flu letter at https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2025-to-2026 • reflect the eligibility for an NHS flu vaccination in 2025/26 • include minor rewording to the Practitioner Authorisation Sheet to reflect UKHSA PGDs	March 2025

This PGD has been developed by the following health professionals:			
Title	Name	Signature	Date
Public Health Pharmacy Adviser (Lead Author) (Durham County Council)	**Claire Jones** *(Senior Pharmacist)*		06/03/2025
Occupational Health Physician (Durham County Council)	**Mark Leeming** *(Senior Doctor)*		04/04/2025
Occupational Health Nurse Manager (Durham County Council)	**Wendy Hall** *(Senior Nurse)*		04/04/2025

This PGD has been developed in conjunction with Community Pharmacy Durham and Sunderland, and in line with DCC PGD Policy.

This PGD has been approved for use in Durham County Council by:			
Title	Name	Signature	Date
Director of Public Health (Durham County Council)	**Amanda Healy** *(Authorising body Governance Authorisation)*		30/04/2025

1. Clinical condition or situation to which the direction applies

Indication

DCC staff members requesting influenza vaccination who meet the inclusion criteria.

Inactivated influenza vaccine is indicated for the active immunisation of DCC employees in accordance with the national immunisation programme and recommendations given in Chapter 19 The Green Book at www.gov.uk/government/publications/influenza-the-green-book-chapter-19, the national flu immunisation programme plan at https://www.gov.uk/government/collections/annual-flu-programme and subsequent correspondence/publications from UK Health Security Agency (UKHSA), NHS England (NHSE), Department of Health and Social Care (DHSC).

Objectives of care

Inactivated influenza vaccine is indicated for the active immunisation of adults for the prevention of influenza infection.

Inclusion criteria

Ensure a valid consent is given before commencing vaccination in line with the standards of the NHS community pharmacy seasonal influenza vaccination advanced service specification. The consent should cover the administration of the vaccine as well as advising the patient of information sharing that will take place for the appropriate recording of their vaccination in their GP practice record. The patient should also be informed that anonymous information regarding their

vaccination will be shared with the Council via the PharmOutcomes data collection platform.

For onsite vaccinations at a pharmacy premises, eligible individuals are those DCC employees who are not eligible for the NHS seasonal influenza vaccination service 2025/26 at the time of the appointment and are aged 18 – 64 years and have shown staff ID.
Note: DCC employees who present to the pharmacy premises for a vaccination and who fall into one of the eligible groups for the NHS seasonal influenza vaccination service 2025/26 at the time of the appointment should access the national NHS flu vaccination programme and PGD.

For off-site vaccinations at a DCC / school premises, eligible individuals are those DCC employees who are aged 18 years and over (since employees aged 18 years and over who are also eligible on the NHS and who present to an off-site clinic at a DCC / school premises can be vaccinated under this DCC service), and who have shown their staff ID.
In addition, for off-site vaccinations only, eligible individuals are those who have pre-completed a pharmacy flu consent form.

For the avoidance of doubt, this PGD specifically does not cover patients, residents or service users and only applies to employed staff of DCC (this includes DCC maintained school staff but not academies).

Exclusion criteria

DCC employees fulfilling one or more of the following criteria are excluded from supply under this PGD:

- No staff ID shown.
- No valid consent in place.
- Under 18 years of age.
- DCC employees who present to the pharmacy premises for a vaccination and who fall into one of the eligible groups for the NHS seasonal influenza vaccination service 2025/26 at the time of the appointment. Note: Staff members aged 18 years and over who are also eligible on the NHS and who present to an off-site clinic at a DCC / school premises can be vaccinated under this DCC service.
- DCC employee acutely unwell/suffering from acute severe febrile illness. In this case vaccination should be postponed until individual has recovered (Without fever or systemic upset the presence of minor infections are not a contra-indication for immunisation and so are not reasons to postpone immunisation).
- Confirmed anaphylactic reaction to a previous dose of an influenza vaccine or a confirmed anaphylactic reaction to any component, ingredient, or excipient of the vaccine (other than ovalbumin). See Cautions / precautions.
- Have already received a dose of an influenza vaccine for the current season.

Refer to current SPC / BNF for full list of details.

Cautions / precautions

- The ability to manage anaphylaxis should be available at all vaccination premises (Chapter 8 of the Green Book at https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8 and advice issued by the Resuscitation Council UK at https://www.resus.org.uk/about-us/news-and-events/anaphylaxis-guidance-vaccination-settings).
- Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route / method).
- Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.
- Individuals with a severe anaphylaxis to egg which has previously required intensive care can be immunised using an egg-free vaccine. Individuals with less severe egg allergy can be immunised 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). See Influenza vaccines marketed in the UK at https://www.gov.uk/government/collections/annual-flu-programme.

Action if excluded / referred for medical advice

- If postponement due to acute illness, aim to arrange a future date for immunisation.
- Document the reason for exclusion and any actions taken.

Action if DCC staff member declines treatment

- A valid consent from the individual must be given for each administration.
- Ensure individual fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine and the risks of infection and disease complications.
- Give advice about the disease, how to recognise it and action required if suspected.
- Document the refusal and any actions taken.

2. Description of treatment

Name, strength and formulation of drug

Inactivated Influenza Vaccine in a Pre-filled Syringe:
Use an inactivated trivalent or quadrivalent influenza vaccine:

adjuvanted egg-grown trivalent influenza vaccine (aTIV)

cell-based trivalent influenza vaccine (TIVc)

recombinant trivalent influenza vaccine (TIVr)
recombinant quadrivalent influenza vaccine (QIVr)

high dose egg-grown trivalent vaccine (TIV-HD)
high dose egg-grown quadrivalent vaccine (QIV-HD)

standard egg-grown trivalent influenza vaccine (TIVe)
egg-grown quadrivalent influenza vaccine (QIVe)

: as described in the annual flu letter at https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2025-to-2026 (with subsequent updates found in the UKHSA Vaccine Update at www.gov.uk/government/collections/vaccine-update).

Legal status

POM – Prescription Only Medicine
Vaccines should be stored according to the conditions detailed in their SPC. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to UKHSA Vaccine Incident Guidance at www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.
Refer to products' SPCs for more information.

Frequency of administration

Annual

Dosage / dose range and frequency

Offer one single dose of a suitable inactivated influenza vaccine for the current annual flu season.

For onsite vaccinations at a pharmacy premises: Offer to those aged 18 – 64 years.
Excludes those 64-year olds becoming age 65 years by 31st March 2026, as they will be eligible under the national NHS flu programme.

Note: DCC employees who present to the pharmacy premises for a vaccination and who fall into one of the eligible groups for the NHS seasonal influenza vaccination service 2025/26 at the time of the appointment should access the national NHS flu vaccination programme and PGD.

For off-site vaccinations at a DCC / school premises: Offer to those aged 18 years and over.
Taking into account vaccine choice for 64-year olds becoming age 65 years by 31st March 2026.
See also Special considerations / additional information section

Route / method

Inactivated influenza vaccines to be given by Intramuscular (IM) injection preferably into the deltoid muscle 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 IM 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 IM injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, IM 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 should be informed about the risk of haematoma from the injection.
- 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.
- Inspect visually prior to administration and ensure appearance is consistent with the description in the SPC for the vaccine being administered.

The SPCs provide further guidance on administration.

Maximum dose and number of treatments

Maximum dose: Dosage is one single dose (all inactivated vaccines)
Maximum number of vaccinations: Dosage is one single dose
Refer to manufacturer's SPC for exact details and Green Book Chapter 19

Follow up treatment / action

- Offer / signpost to the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
- 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 Covid-19 or other respiratory viruses that circulate during the flu season.
- Inform the individual of possible side effects and their management.
- The individual should be advised when and where to seek appropriate advice in the event of an adverse reaction.
- Inform the GP if an adverse reaction is deemed to be clinically significant.
- In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed.

3. Further aspects of treatment

Relevant warnings and potential adverse effects

- 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 IM 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 detailed list of adverse reactions associated with inactivated influenza vaccine is available in the SPC for each vaccine and in the Green Book Chapter 19.

Drug interactions

A detailed list of drug interactions associated with inactivated influenza vaccine is available in the SPC for each vaccine at https://www.medicines.org.uk/emc.

Reporting procedure of adverse effects

- Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme at http://yellowcard.mhra.gov.uk.
- Where inactivated influenza vaccines are black triangle (See SPCs at https://www.medicines.org.uk/emc for indication of current black triangle status), any suspected adverse reactions to these products should be reported via the Yellow Card Scheme.
- Adverse reactions to a vaccine should be documented and the individual's GP should be informed if the reaction is deemed to be clinically significant.

Identification and management of adverse reactions

- Individual requested to report side effects.
- Advice on management including anaphylaxis: Chapter 8 of the Green Book at https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8 and advice issued by the Resuscitation Council UK at https://www.resus.org.uk/about-us/news-and-events/anaphylaxis-guidance-vaccination-settings provides detailed advice on managing adverse effects following immunisation. The registered practitioner should have immediate access to adrenaline 1 in 1000 injection and access to a telephone at the time of vaccination.
- Refer to GP if appropriate.

Refer to current SPC "special warnings & special precautions for use" section for full details.

Records

Information to be recorded on PharmOutcomes as set out in the preferred provider contract with DCC and to be retained according to legal and professional obligations.

Manual or computerised records and data collection should include:

- Confirmation that a valid consent has been given
- DCC staff member name, home address, DoB and GP practice
- Location if off-site clinic at DCC or DCC-maintained school premises
- Brand name, batch number and expiry date of vaccine
- Date of administration
- Registered practitioner name and registration number
- Details of any significant adverse drug reactions and actions taken

A record of the vaccination should be returned to the individual's GP practice via PharmOutcomes notification on the same day that it is administered unless exceptional circumstances apply.

Special considerations / additional information

- Vaccines should be allowed to reach room temperature before use. Suitable cold chain arrangements should be in place for the transport of the vaccines.
- Store between +2°C to +8°C. Do not freeze. Store in original packaging. The vaccine should be protected from light at all times (exposure may inactivate the virus).
- Have access to the current DCC influenza vaccines PGD, and the latest SPC and BNF.
- 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 Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste at https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/.
- The registered practitioner should have immediate access to adrenaline 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 should consent to information sharing with their GP practice as part of the consent process for accessing this service.
- The registered practitioner should manage flu vaccinations in line with the latest national guidance at https://www.gov.uk/government/collections/annual-flu-programme.

4. Characteristics of healthcare professional using this PGD

Only registered practitioners that have been specifically authorised by the authorising manager may use this PGD for the indications defined within it.

Qualification/registration requirements

Practitioners must only work under this PGD where they are competent to do so.
Practitioners working to this PGD must also be one of the registered professionals who can legally supply and administer under a PGD as described in Schedule 16 of The Human Medicines Regulations 2012 at https://www.legislation.gov.uk/uksi/2012/1916/schedule/16.
For example:
Pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council.
Nurses currently registered with the Nursing and Midwifery Council.

Additional requirements

The registered practitioner must:

- Be authorised by name as an approved practitioner under the current terms of this PGD before working under its authority (i.e. by signing and retaining the PGD practitioner authorisation sheet).
- Have undertaken appropriate training and maintain accreditation for working under PGDs for supply/administration of medicines as required by the NHS community pharmacy seasonal influenza vaccination advanced service specification and a declaration of competence for vaccination services, as either defined by CPPE at www.cppe.ac.uk/services/declaration-of-competence for registered pharmacists and technicians, or by the UKHSA flu vaccinator competency assessment tool at https://www.gov.uk/government/publications/flu-immunisation-training-recommendations.
- Meet the National Minimum Standards and Core Curriculum for Immunisation Training as described in the Flu immunisation training recommendations at https://www.gov.uk/government/publications/flu-immunisation-training-recommendations.
- Be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs at www.nice.org.uk/guidance/mpg2/resources).
- Maintain knowledge of vaccination products and be alert to changes in their SPC, The Green Book, and the national immunisation programme (in particular the 'Information for Healthcare Practitioner' document at https://www.gov.uk/government/collections/annual-flu-programme).

- Be competent to undertake immunisation and to discuss issues related to immunisation.
- Be competent in the handling and storage of vaccines and management of the "cold chain".
- Have up to date resuscitation skills, anaphylaxis training and be competent to recognise and manage anaphylaxis.
- Have immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination.
- Have access to PharmOutcomes, current BNF, and the PGD and associated online resources.
- For off-site vaccinations, have the appropriate professional indemnity insurance.

THE REGISTERED PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT DCC AUTHORISED VERSION OF THIS PGD BEFORE WORKING UNDER ITS AUTHORITY.

Continued training requirements

- Registered practitioners should ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, in line with the community pharmacy seasonal influenza vaccination advanced service and with evidence of appropriate Continuing Professional Development.
- Registered practitioners should be constantly alert to any subsequent recommendations from UKHSA and/or NHSE and other sources of medicines information. The most current national recommendations should be followed.
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Key references

Inactivated influenza vaccination

- Immunisation Against Infectious Disease: The Green Book, Chapter 19. www.gov.uk/government/publications/influenza-the-green-book-chapter-19
- Collection: Annual Flu Programme. www.gov.uk/government/collections/annual-flu-programme
- Community Pharmacy England information on the Community Pharmacy Seasonal Influenza Vaccine Service https://cpe.org.uk/national-pharmacy-services/advanced-services/flu-vaccination-service/
- Declarations of competence for vaccination services at www.cppe.ac.uk/services/declaration-of-competence and https://www.gov.uk/government/publications/flu-immunisation-training-recommendations
- BNF. https://bnf.nice.org.uk/.
- Summary of Product Characteristics https://www.medicines.org.uk/emc

General

- Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste. NHSE. https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/
- National Minimum Standards and Core Curriculum for Immunisation Training. 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. www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: Competency framework for health professionals using patient group directions www.nice.org.uk/guidance/mpg2/resources
- Vaccine Incident Guidance. www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors
- Management of anaphylaxis. Chapter 8 of the Green Book. https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8. Advice issued by the Resuscitation Council UK. https://www.resus.org.uk/about-us/news-and-events/anaphylaxis-guidance-vaccination-settings.

Management and Monitoring of Patient Group Direction

The Administration of Influenza (Seasonal Flu) Vaccines

PRACTITIONER AUTHORISATION SHEET

Pharmacy Influenza Vaccination PGD DCC 2025 / 0001. Valid from: 01/10/2025 Expiry: 31/03/2026

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within the PGD and the accompanying service specification.

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. I have completed all the necessary and appropriate training, including a Declaration of Competence, which will allow me to provide this professional service while this PGD remains valid.

Name	Registration number	Signature	Date

Authorising manager

I confirm that the registered practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of _____ for the above named registered practitioners who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Remove any unused rows in the list of practitioners to prevent additions post managerial authorisation.

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

The final authorised copy of this PGD should be kept by contractors for 8 years after the PGD expires.