NHS Greater Glasgow and Clyde

Administration of inactivated influenza vaccine 2024/25 season

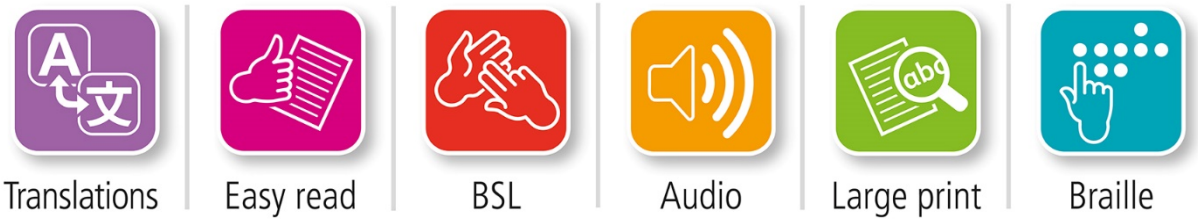
Patient group direction (PGD) template

Publication date: 19 August 2024

PGD No: 2024/2713

Expiry date: 31 August 2025

Version 1.0



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Most recent changes

Version	Date	Summary of changes
1.0	19 August 2024	The following changes to the 2023/24 season PGD have been made: • minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs • dates changed for 2024/25 season. • Inclusion criteria section updated to generic inclusion criteria. • Name of medicine/form/strength section updated to simplified information on eligible group and current recommended influenza vaccine for national programme. • Green book advice on co-administration with respiratory syncytial virus (RSV) vaccine added.

Contents

Authorisation

PGD administration of inactivated influenza vaccine

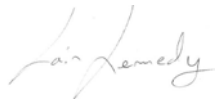
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer inactivated influenza vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

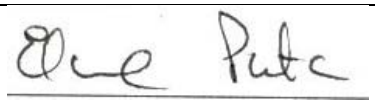
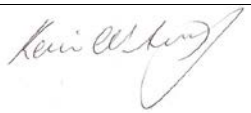
NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS Greater Glasgow and Clyde by:

Professionals drawing up PGD/Authors	
*Name: Sarah Marshall  Signature: Date: 21/08/2024	Designation: Specialist Pharmacist Public Health E-mail address: **sarah.marshall4@ggc.scot.nhs.uk**
Name: Tina McMichael  Signature: Date: 21/08/2024	Designation: Health Protection Nurse Specialist E-mail address: **tina.mcmichael2@ggc.scot.nhs.uk**

Name: Iain Kennedy  Signature: Date: 21/08/2024	Designation: Consultant in Public Health E-mail address: **Iain.kennedy@ggc.scot.nhs.uk**

Approved on behalf of NHS Greater Glasgow and Clyde by ADTC Patient Group Direction Sub Committee representatives:

Chair	Dr Craig Harrow	
Senior Pharmacist	Elaine Paton, Senior Prescribing Adviser	
Nurse Director Representative	Kevin McAuley, Lead Nurse North Sector	

Valid from: 1 September 2024 Expiry date: 31 August 2025

1. Clinical situation

1.1. Indication

Active immunisation against disease caused by influenza virus in line with Scottish Government immunisation programme and JCVI advice/recommendations as set out in Green Book **Chapter 19** and subsequent correspondence/publications from Scottish Government.

1.2. Inclusion criteria

Valid consent has been given to receive the vaccine.

Vaccine should be offered to individuals invited, or eligible in accordance with the recommendations in Green Book **Chapter 19**, and/or in line with **Scottish Government seasonal influenza vaccination programme** and subsequent correspondence/publications from Scottish Government.

National policy must be followed in relation to the groups eligible for vaccination at a particular point in time.

Individuals who have received a haematopoietic stem cell transplant or CAR-T therapy and who require revaccination, in accordance with the **Scottish Haematology Society Revaccination Schedule.**

1.3. Exclusion criteria

Individuals who:

- Are aged under 6 months.
- Have had a confirmed anaphylactic reaction to a previous dose of influenza vaccine.
- Have had a confirmed anaphylactic reaction to any component of influenza vaccine. Different brands may contain traces of neomycin, kanamycin, formaldehyde and other excipients – practitioners must check the marketing authorisation holder's SmPC for the particular brand.
- Have a history of confirmed anaphylactic reaction to eggs/egg product or chicken proteins such as ovalbumin where vaccine was produced using eggs.
- Have a history of severe (i.e. anaphylactic) reaction to latex where vaccine is not latex free.

- Are suffering from an acute febrile illness (the presence of a minor infection is not a contraindication for immunisation).

1.4. Cautions/need for further advice/circumstances when further advice should be sought from a doctor

The Green Book advises that there are very few individuals who cannot receive inactivated influenza vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation coordinator or health protection team.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Co-administration with other vaccines

Inactivated influenza vaccine can be given at the same time as other vaccines including COVID-19 vaccines.

In older adults (aged 75-79 years) it is recommended that RSV vaccine is not routinely scheduled to be given at the same appointment or on the same day as an influenza or COVID-19 vaccine. No specific interval is required between administering the vaccines. If it is thought that the individual is unlikely to return for a second appointment or immediate protection is necessary, RSV vaccine can be administered at the same time as influenza and/or COVID-19 vaccination.

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.

Syncope

Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents 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.

1.5 Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

Name of medicine

Inactivated influenza vaccine suspension for injection in a pre-filled syringe, including:

- adjuvanted quadrivalent influenza vaccine▼ (aQIV) (Seqirus vaccines).
- cell-based quadrivalent influenza vaccine▼ (QIVc) (Seqirus vaccines).

Eligible Group and current recommended influenza vaccine for national programme:

Aged 65 years and over (including those 64 year olds who are 65 years old by 31 March 2025)

Offer Adjuvanted quadrivalent influenza vaccine▼ (aQIV)

Eligible individuals aged from six months to under 65 years

Offer Cell-based quadrivalent influenza vaccine▼ (QIVc) (Seqirus vaccines).

Revaccination of individuals who have received a haemopoietic stem cell transplant or CAR-T treatment

Please refer to age-based recommendation for vaccine choice as set out above.

2.2. Route of administration

Administer by Intramuscular injection.

The preferred site for children older than 12 months or adults is deltoid area of upper arm. The preferred site for infants is anterolateral thigh.

Adjuvanted quadrivalent influenza vaccine▼ (aQIV) (Seqirus vaccines), cell-based quadrivalent influenza vaccine ▼(QIVc) (Seqirus vaccines)) must only be administered via the intramuscular route.

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 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. 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 (23 or 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/parent/carer should be informed about the risk of haematoma from the injection.

The vaccine should be visually inspected for particulate matter and discolouration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

2.3. Dosage

0.5ml

2.4. Frequency

Single dose.

Children aged six months to less than nine years in clinical risk group who have not received influenza vaccine before should receive a second dose of vaccine at least four weeks after the first dose.

Children aged six months to less than nine years who are not in clinical risk groups should be offered a single dose, even if they have not previously received influenza vaccine.

Revaccination of individuals who have received a haemopoietic stem cell transplant or CAR-T treatment

In accordance with the schedule recommended by the Scottish Haematology Society **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment**

2.5. Duration of treatment

See above.

2.6. Maximum or minimum treatment period

See above.

2.7. Quantity to supply/administer

See above.

2.8. ▼ black triangle medicines

Yes, the following vaccines are ▼:

Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines).

Adjuvanted quadrivalent influenza vaccine▼ (aQIV) (Seqirus vaccines).

This information was accurate at the time of writing. See product SmPCs at www.medicines.org.uk for indication of current black triangle status.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use outwith the SmPC?

Yes.

Adjuvanted quadrivalent influenza vaccine▼ (aQIV) is licensed for administration to individuals aged 65 years and over. It may be administered under this PGD to those people who are 64 years old at the point of immunisation but are 65 years by 31 March 2025.

Revaccination of individuals following haematopoietic stem cell transplant of CAR-T treatment is considered off-label but is in accordance with the **Scottish Haematology Society schedule.**

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines or Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.

2.11. Storage requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Store in the original packaging to protect from light.

Do not freeze.

NHS Board guidance on storage and handling of vaccines should be observed.

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.

2.12. Additional information

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.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

Pain, swelling or redness at the injection site, low grade fever, malaise, shivering, fatigue, headache, aching muscles and joint pain are among the commonly reported symptoms after vaccination. A small painless nodule (induration) may also appear at the injection site. These symptoms usually disappear within one to two days without treatment.

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of a severe adverse reaction individual should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **https://yellowcard.mhra.gov.uk/**

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individual:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Immunisation promotional material may be provided as appropriate

Individual advice/follow-up treatment:

- Inform the individual/carer of possible side effects and their management.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on **https://yellowcard.mhra.gov.uk/**
- Give general advice relating to good hygiene practice to prevent the spread of germs – always have tissues to hand, use a clean tissue to cover your mouth and nose when you cough and/or sneeze, bin any tissue after one use, wash your hands with soap and hot water or a sanitiser gel often.
- When applicable, advise individual/parent/carer when the subsequent dose is due.

3.4. Observation following vaccination

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

Following immunisation, patients remain under observation in line with NHS board policy.

3.5. Follow up

As above.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC)
- 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.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.

- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/SmPC.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

Employer

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included.

If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

5. Audit trail

Record:

- that valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

Practitioners operating the PGD must be familiar with:

- **Immunisation against Infectious Disease [Green Book]**
- **Immunisation against Infectious Disease [Green Book] chapter 19**
- Current edition of British National Formulary (BNF) and BNF for children
- Marketing authorisation holder's Summary of Product Characteristics
- **Educational resources for registered professionals produced by National Education for Scotland**
- All relevant Scottish Government advice including the relevant CMO letter(s)
- **Professional Guidance on the Administration of Medicines in Healthcare Settings 2019**
- **Professional Guidance on the Safe and Secure Handling of Medicines**
- **Scottish Haematology Society advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment**

7. PGD for administration of influenza vaccine (inactivated) for 2024/25 season - authorisation V1.0 (valid from 1 September 2024 and expires 31 August 2025): authorisation

Practitioner

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's SmPC for all vaccines administered in accordance with this PGD.

By signing this Patient Group Direction, you are indicating that you agree to its contents and that you will work within it.

I agree to administer influenza vaccine (inactivated) vaccine only in accordance with this PGD.

Name of professional	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 **NHS Greater Glasgow & Clyde** for the above-named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area:

Name ……

Signature ……..

Date ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

8. Version history

Version	Date	Summary of changes
1.0	19 August 2024	The following changes to the 2023/24 season PGD have been made: • minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs • dates changed for 2024/25 season. • Inclusion criteria section updated to generic inclusion criteria. • Name of medicine/form/strength section updated to simplified information on eligible group and current recommended influenza vaccine for national programme. • Green book advice on co-administration with respiratory syncytial virus (RSV) vaccine added.

9. Appendix 1: Seasonal Influenza Vaccine PGDs 2024-25 – UK Licensed Influenza Vaccines

Manufacturer / supplier	Name of product	Vaccine type	Age indication	Ovalbumin content	Latex Formaldehyde Other	Amino-glycosides
Astra Zeneca UK Ltd	Fluenz LAIV	Trivalent live attenuated influenza vaccine – nasal spray suspension	From 24 months to less than 18 years of age	Less than 0.024 micrograms per 0.2 ml dose	Latex free[1] Contains gelatin (porcine) Formaldehyde free	Gentamicin[3]
Seqirus	Cell-based Quadrivalent Influenza Vaccine (Surface Antigen, Inactivated) Seqirus suspension (QIVc)	Cell grown quadrivalent influenza vaccine – surface antigen inactivated prepared in cell cultures	From six months (off label)	Not applicable – egg free	Latex free Formaldehyde free	Not applicable
Seqirus	Adjuvanted Quadrivalent Influenza Vaccine (Surface Antigen, Inactivated) Seqirus suspension for injection (aQIV)	Adjuvanted quadrivalent influenza vaccine – surface antigen, inactivated – adjuvanted with MF59C.1	From 65 years	Equal to or less than 1 micrograms per 0.5 ml dose	Latex free[2] Risk of formaldehyde residue	Kanamycin[3] Neomycin[3]

Notes

None of the influenza vaccines for the 2024-25 season contain thiomersal as an added preservative.

1. No latex is present in the product but manufacturer is unable to confirm if latex has come into contact with the product during the manufacturing process.

2. None of the components of the staked needle prefilled syringe presentation that are in direct contact with the vaccine (syringe barrel, plunger and rubber stopper) are made with natural rubber latex. The needle shield contains natural rubber latex.

Green Book, Chapter 6 states it is theoretically possible that latex protein from these tip caps, plungers or vial stoppers may cause allergic reactions when the vaccines are administered to latex-sensitive individuals. There is little evidence that such a risk exists and any such risk would be extremely small. The Green Book chapter states as a precaution, if an individual has a history of severe (i.e. anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain latex should not be administered, unless the benefit of vaccination outweighs the risk of an allergic reaction to the vaccine. Where possible, an alternative latex-free vaccine that covers the same disease should be administered.

3. Cross sensitivity to aminoglycosides is common, assume potential reaction for all, if allergic response to one has been demonstrated.

Ovalbumin, latex and aminoglycoside content for vaccines are correct as at 29 July 2024, however, these may be subject to change in manufacturing practice at any time.