

Patient Group Direction (PGD) Template

**Administration of inactivated influenza vaccine
2021/22 season**

Publication date: 17/08/2021

PGD number: 2021/2225

Version history

Version	Date	Summary of changes
1.0	17/08/21	<p>This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs</p> <p>The following changes from the PGD used in 2020-21 have been made:</p> <ul style="list-style-type: none">• Indication section updated for dates for 2021-22 season• Inclusion criteria section updated to include cohorts eligible in 2021-22 season• Exclusion section updated with details of vaccines used in 2021-22• Name of medicine section updated to reflect vaccines procured for 2021-22 programme• ▼additional monitoring section updated with details of vaccines used in 2021-22• Use outwith SPC section updated for dates for 2021-22 season• Additional information section updated to state that vaccine can be given at the same time as COVID-19 vaccines.• References section has been updated

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Authorisation

PGD administration of inactivated influenza vaccine

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 marketing authorisation holder's summary of product characteristics (SPC) 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:

Doctor Dr Gillian Penrice, Consultant in Public Health

Signature



Pharmacist Val Reilly, Public Health Protection Pharmacist

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Nurse Hilda Cruikshanks (Health Protection Nurse Specialist)

Signature -



Date 18/08/2021

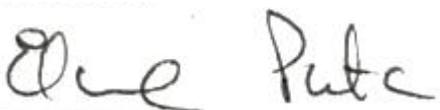
Approved on behalf of NHS Greater Glasgow and Clyde by ADTC Patient Group Direction Sub Committee representatives:

Chair. Dr Craig Harrow Signature



Senior Pharmacist Elaine Paton, Senior Prescribing Adviser

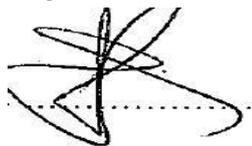
Signature -



Nurse Director:

Representative: John Carson, Lead Nurse North Sector

Signature -

A handwritten signature in black ink, appearing to be 'John Carson', written over a horizontal dashed line.

Date: 18/08/2021

Effective from: 01/09/2021

Review date: 31/08/2022

Clinical situation

Category	Description
Indication	Active immunisation against disease caused by influenza virus in line with Scottish Government seasonal influenza immunisation programme 2021-22
Inclusion criteria	<p>Individuals aged 65 years or above on 31 March 2022.</p> <p>Individuals aged 50 years to 64 years on 31 March 2022.</p> <p>Individuals aged six months to under 50 years identified in the Scottish Government's seasonal influenza vaccination programme 2021-22 in the clinical risk groups laid out in CMO seasonal influenza immunisation programme letter programme letter and those who are considered clinically extremely vulnerable.</p> <p>Pregnant women at any stage of pregnancy (first, second or third trimester), irrespective if received influenza vaccine in a previous pregnancy</p> <p>Individuals in whom live attenuated intranasal influenza vaccine is not suitable</p> <p>Adult household contacts of immunosuppressed individuals</p> <p>Individuals with an underlying disease where the risk from influenza infection may exacerbate their condition or result in serious illness from influenza itself.</p> <p>Those 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 university halls of residence etc.)</p> <p>Unpaid carers and young carers, defined as, someone who, without payment provides help and support to a partner, child, relative, friend or neighbour, who could not manage without their help. This could be due to age, physical or mental illness, addiction or disability. A young carer is a child or young person under the age of 18 carrying out significant caring tasks and assuming a level of responsibility for another person, which would normally be taken by an adult.</p> <p>Health care workers who are in direct contact with patients and service users.</p> <p>Social care workers who provide direct personal care in the following settings: adult care home; children's residential or secure care; or care at home including personal assistants</p> <p>NHS Independent contractors and support staff (GP, dental, optometry practices, community pharmacies and laboratory staff working on COVID-19 testing)</p>

Category	Description
	<p>Nursery, Primary and Secondary School Teachers and support staff</p> <p>Prison population</p> <p>Prison officers/staff who deliver front facing detention services</p> <p>Valid consent has been given to receive the vaccine.</p>
Exclusion criteria	<p>Children under 6 months.</p> <p>Confirmed anaphylactic reaction to a previous dose of influenza vaccine.</p> <p>Confirmed anaphylactic reaction to any component of influenza vaccine.</p> <p>Different brands may contain traces of neomycin, gentamicin, kanamycin, polymixin B, formaldehyde and other excipients – practitioners must check the marketing authorisation holder’s SPC for the particular brand.</p> <p>History of confirmed anaphylactic reaction to eggs/egg product or chicken proteins such as ovalbumin where vaccine was produced using eggs.</p> <p>History of severe (i.e. anaphylactic) reaction to latex where vaccine is not latex free.</p> <p>Acute febrile illness – consider postponing immunisation until patient has fully recovered.</p> <p>Some influenza vaccines (inactivated) are restricted to use in particular age groups.</p> <p>Practitioners must be familiar with and refer to the marketing authorisation holder’s SPC for the particular brand when administering vaccines:</p> <ul style="list-style-type: none"> • Adjuvanted quadrivalent influenza vaccine ▼(aQIV) (Seqirus vaccines) is licensed from 65 years • Cell-based quadrivalent influenza vaccine ▼(QIVc) (Seqirus vaccines) is licensed from age 2 years • Quadrivalent influenza vaccine (Sanofi Pasteur) (egg grown QIV) (QIVe) is licensed from 6 months
Cautions/need for further advice/ circumstances when further advice should be	<p>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 or health protection team.</p>

Category	Description
sought from a doctor	<p>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.</p> <p>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.</p>
Action if excluded	<p>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.</p> <p>Document the reason for exclusion and any action taken in accordance with local procedures</p> <p>Inform or refer to the clinician in charge at the clinic or GP as appropriate.</p> <p>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.</p>
Action if patient declines	<p>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.</p> <p>Document advice given and decision reached. In NHS clinic setting, inform or refer to the clinician in charge. In GP practice setting, inform or refer to GP.</p>

Description of treatment

Name of medicine

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

- adjuvanted quadrivalent influenza vaccine ▼ (aQIV) (Seqirus vaccines)
- cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines)
- egg-grown quadrivalent influenza vaccine (QIVe) (Sanofi Pasteur)

Table showing current recommended influenza vaccine for national programme

Eligible Group	Current recommended influenza vaccine for national programme
6 months to less than 2 years	Offer Sanofi Pasteur Quadrivalent influenza vaccine (egg based QIV)
2 years to under 18 years (unsuitable for LAIV)	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines)
Aged 18 years to under 50 years in clinical risk group	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines)
Aged 50-64 years (including those who are 50 years old by 31 March 2022)	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines)
Aged 65 years and over (including those 64 year olds who are 65 years old by 31 March 2022)	Offer Adjuvanted quadrivalent influenza vaccine ▼ (aQIV)
Health and social care staff	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines)
Unpaid/young carers	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines)
Nursery, Primary and secondary School Teachers and support staff	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines)
Prison population and Prison officers	Offer Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines)

Note: Adjuvanted QIV should preferably be used as appropriate for those aged 65 years and over.

Note: LAIV could be used as appropriate for those aged under 18 years – see Fluenz Tetra PGD

Category	Description
Form/strength	Suspension for injection.
Route of administration	<p>Administer by Intramuscular injection.</p> <p>Adjuvanted quadrivalent influenza vaccine ▼ (aQIV) and cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines) must only be administered via the intramuscular route.</p> <p>Influenza vaccines licensed for intramuscular or subcutaneous administration such as Sanofi Pasteur egg based quadrivalent influenza vaccine (QIVe) may alternatively be administered by the subcutaneous route.</p> <p>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.</p> <p>Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (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.</p> <p>Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (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</p>
Dosage	Single dose of 0.5ml
Frequency	Children aged six months to less than nine years who have not received influenza vaccine before should receive a second dose of vaccine at least four weeks later.
Duration of treatment	Not applicable.
Maximum or minimum treatment period	Not applicable.

Category	Description
Quantity to supply/ administer	Not applicable.
▼ additional monitoring	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 SPCs at www.medicines.org.uk for indication of current black triangle status.
Legal category	Prescription Only Medicine (POM)
Is the use out with the SPC?	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 2022 in accordance with the Scottish Government seasonal influenza immunisation programme 2021/22 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.
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.
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. Before each dose is administered the vaccine should be shaken well. Inactivated influenza vaccine can be given at the same time as other vaccines including COVID-19 vaccines but 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 is given should be recorded in the individual's record.

Warnings

Category	Description
Adverse reactions and management	<p>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.</p> <p>For full details/information on possible side effects, refer to the marketing authorisation holder's SPC.</p> <p>As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.</p> <p>In the event of a severe adverse reaction individual should be advised to seek medical advice.</p>
Reporting procedure for adverse reactions	<p>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 http://yellowcard.mhra.gov.uk/</p> <p>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.</p>

Category	Description
Advice to patient or carer including written information	<p>Written information to be given to individual</p> <ul style="list-style-type: none"> • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Immunisation promotional material may be provided as appropriate <p>Individual advice / follow up treatment</p> <ul style="list-style-type: none"> • Inform the individual/carers of possible side effects and their management. • Give advice about post vaccination fever in the context of COVID-19 pandemic in accordance with advice from Scottish Government. • Give advice regarding normal reaction to the injection e.g. sore arm is possible. • 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: http://yellowcard.mhra.gov.uk • In children, give advice on monitoring of temperature and use of measures to lower temperature (such as giving paracetamol). • 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.
Monitoring	Following immunisation patients remain under observation in line with NHS board policy.
Follow-up	Not applicable.
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.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	<p>The following classes of registered healthcare practitioners are permitted to administer this vaccine</p> <ul style="list-style-type: none"> • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists 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.
Specialist competencies or qualifications	<p>Persons must only work under this PGD where they are competent to do so.</p> <p>All persons operating this PGD:</p> <ul style="list-style-type: none"> • 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 manufacturers product information/summary of product information, • 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 <p>Employer</p> <p>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.</p> <p>As a minimum, competence requirements stipulated in the PGD must be adhered to.</p>

Category	Description
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.

Audit trail

Category	Description
Record/audit trail	<p>Record:</p> <ul style="list-style-type: none"> • 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 for vaccine • name of person that 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 <p>Records should be kept 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.</p>
Additional references	<p>Practitioners operating the PGD must be familiar with:</p> <ul style="list-style-type: none"> • 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

Category	Description
	<ul style="list-style-type: none"> • Marketing authorisation holder's Summary of Product Characteristics • <u>Educational resources for registered professionals produced by National Education for Scotland</u> • All relevant Scottish Government advice including the relevant CMO letter(s) • <u>Professional Guidance on the Administration of Medicines in Healthcare Settings 2019</u> • <u>Professional Guidance on the Safe and Secure Handling of Medicines</u>

PGD for administration of influenza vaccine (inactivated) – 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 summary of product characteristics 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) 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 **[insert name of organisation]** 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.

Appendix 1: Seasonal Influenza Vaccine PGDs 2021-22 - UK Licensed Influenza Vaccines

Manufacturer/ supplier	Name of product	Vaccine type	Age indication	Ovalbumin content per 0.5ml dose	Latex Formaldehyde Other	Amino- glycosides
Astra Zeneca UK Ltd	Fluenz Tetra® LAIV	Quadrivalent live attenuated influenza vaccine – nasal spray suspension	From 24 months to less than 18 years of age	≤0.024 µg (0.2ml dose)	Latex free ¹ Contains gelatin (porcine) Formaldehyde free	Gentamicin ³
Sanofi Pasteur	Quadrivalent Influenza Vaccine QIVe	Standard egg grown quadrivalent influenza vaccine – split virion inactivated	From 6 months	≤0.05 µg	Latex free Risk of formaldehyde residue	Neomycin ²
Seqirus	Flucelvax Tetra ®▼ QIVc	Cell grown quadrivalent influenza vaccine – surface antigen inactivated prepared in cell cultures	From 2 years	Not applicable – egg free	Latex free ² Formaldehyde free	Not applicable
	Fluad Tetra ®▼ aQIV	Adjuvanted quadrivalent influenza vaccine – surface antigen, inactivated – adjuvanted with MF59C.1	From 65 years	≤1 µg	Latex free ² Risk of formaldehyde residue	Kanamycin ³ Neomycin ³

Notes

None of the influenza vaccines for the 2021 to 2022 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.

Chapter 6 of the Green Book 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 **09 August 2021**, however, these may be subject to change in manufacturing practice at any time.

Acknowledgement - this appendix has been produced based on a previous version produced by NHS Greater Glasgow and Clyde.