Patient Group Direction

For health professionals legally permitted to operate under a PGD

Administration of
INACTIVATED INFLUENZA VACCINE (INJECTABLE)
to individuals aged 6 months and upwards

(EXCLUDES LIVE ATTENUATED INTRANASAL VACCINE)

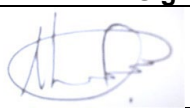
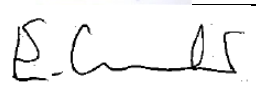
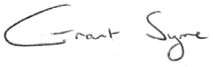
Number **263**

Issued **August 2022**

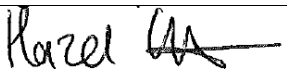
Issue Number **4.0**

Date of review **August 2023**

It is the responsibility of the person using this PGD to ensure that they are using the most recent issue.

Developed by	Designation	Signature	Date
Athan Tachtatzis	PGD Pharmacist, NHS Fife		09.08.22
Dr Esther Curnock	Consultant in Public Health Medicine, NHS Fife		18.08.22
Charmaine Bremner	Interim Lead Nurse Immunisation Services NHS Fife		01.09.22
Grant Syme	Consultant Physiotherapist Physiotherapy NHS Fife		11.08.22

THIS PATIENT GROUP DIRECTION HAS BEEN APPROVED BY:

Name	Designation	Signature	Date
Nicola Robertson	Associate Director of Nursing NHS Fife		01.09.22
Dr Aylene Kelman	Clinical Director H&SCP NHS Fife		01.09.22
Hazel Close	Lead Pharmacist Public Health NHS Fife		24.08.22

1. Clinical condition to which the patient group direction applies

Indication	• Active immunisation against disease caused by influenza virus in line with Scottish Government seasonal influenza immunisation programme 2022-23.
Inclusion criteria	• Valid consent to treatment according to NHS Fife policy Influenza vaccine should be offered to individuals defined as eligible in accordance with Scottish Government's seasonal influenza vaccination programme 2022-23 as set out in Scottish Government seasonal influenza immunisation programme letter. This includes: • Individuals aged 65 years or above on 31 March 2023. • Individuals aged 50 years to 64 years on 31 March 2023. • Individuals aged six months to under 50 years in clinical risk groups identified in Annex A of the Scottish Government seasonal influenza immunisation programme letter. • Pregnant women at any stage of pregnancy (first, second or third trimester), irrespective if received influenza vaccine in a previous pregnancy • Individuals in whom live attenuated intranasal influenza vaccine is not suitable • Adult household contacts of immunosuppressed individuals • Individuals with an underlying disease where the risk from influenza infection may exacerbate their condition or result in serious illness from influenza itself. • 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). • Those who are in receipt of carer's allowance or 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. • Health care workers who are directly involved in delivering care. • Social care workers who provide direct personal care in the following settings: residential care for adults; children's residential and secure care for children; or community care for persons at home including housing support and personal assistants. • NHS Independent contractors and support staff (GP, dental, optometry practices, community pharmacies and Non-NHS laboratory staff (if working on COVID-19

	testing) and support staff. • Nursery, Primary and Secondary School Teachers and support staff • Prison population • Prison officers/support staff delivering direct detention services
Exclusion criteria	• No valid consent to treatment according to NHS Fife policy 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, gentamicin, kanamycin, polymixin B, 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). Some influenza vaccines (inactivated) are restricted to use in particular age groups. Practitioners must be familiar with and refer to the marketing authorisation holder's SmPC for the particular brand when administering vaccines: • 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 / 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 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. 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. • It is the responsibility of the designated, authorised staff using this PGD to ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt, advice should be sought and recorded before the drug is administered / supplied. • Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation
Action if excluded	• Do not use the PGD 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 at the clinic or GP as appropriate. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.
Action if patient declines treatment	• 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 • In NHS clinic setting, inform or refer to the clinician in charge. In GP practice setting, inform or refer to GP. If further advice is required, discuss with Consultant in Public Health as appropriate

2. Medication Details

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) •

Age/Group	**Current recommended influenza vaccine for national programme**
6 months to less than 2 years	Offer Sanofi Pasteur Quadrivalent influenza vaccine (egg based QIVe)
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 2023	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 31st March 2023	Offer Adjuvanted quadrivalent influenza vaccine▼ (aQIV)
Health and social care staff/workers	Offer Cell-based quadrivalent influenza vaccine ▼(QIVc) (Seqirus vaccines)
Carers/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)
Independent contactors	Offer Cell-based quadrivalent influenza vaccine▼ (QIVc) (Seqirus vaccines)

Note: Adjuvanted quadrivalent influenza vaccine▼ (aQIV) 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

Form/Strength	• Suspension for injection
Route of administration	• Intramuscular injection • The preferred site for children older than 12 months and adults is the deltoid area of the upper arm. The preferred site for infants is anterolateral thigh • Adjuvanted quadrivalent influenza vaccine▼ (aQIV) and 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 who's latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 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 individuals anticoagulation therapy • Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (equal to 23 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 • Influenza vaccines licensed for intramuscular or subcutaneous administration such as Sanofi Pasteur egg based quadrivalent influenza vaccine (QIVe) should be administered via the intramuscular route except where there is a bleeding disorder and then the deep subcutaneous route should be used to reduce the risk of bleeding • 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.
Dosage	Single dose of 0.5ml
Frequency of administration	ONE dose - except for children aged 6 months to less than 9 years who have not received influenza vaccine before who should receive a second dose of vaccine at least 4 weeks after the first
Duration of treatment including maximum/ minimum period if applicable	Not applicable
Quantity to be supplied/administered	Not applicable
Patient advice verbal and written	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 • 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

	• Advise individual to seek medical advice in case of 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 appropriate dose of 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
Black triangle medicine ▼	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 http://www.medicines.org.uk for indication of current black triangle status.
Legal category	POM - prescription only medicine
Use outwith 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 administration but who will be 65 years by 31st March 2023 in accordance with Scottish Government Seasonal Influenza Immunisation Programme 2022-23 • 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 pharmacy where vaccines will be assessed following HPS incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under PGD is allowed • 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.
Storage requirements	• Between +2 to +8°C • Contact Pharmacy for advice if stored out with +2°C to +8°C • There may be circumstances when vaccines stored out with the recommended storage temperatures of +2 to +8°C can be administered providing the product has been confirmed as suitable for use by the manufacturers and Pharmacy • If the vaccine has been frozen, it must not be used and pharmacy must be contacted for advice • NHS Fife guidance on Storage and Handling of vaccines should be observed • Transportation must be in cool-boxes that have been tested and validated for use by NHS Fife Pharmacy • Store in the original packaging • Ensure within expiry date • 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 including possible adverse reactions and management of these	• Pain, swelling, 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 SPC • 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
Identification and management of adverse reactions	• All suspected serious reactions should be reported directly to the MHRA/Commission on Human Medicines through the Yellow Card scheme and recorded in the patient's medical notes. Reports should be made online at https://yellowcard.mhra.gov.uk • Any serious adverse reaction to the vaccine should be documented in an individual's record. GP/Clinician should also be informed
Monitoring if required	• Following immunisation patients remain under observation in line with NHS Fife policy
Additional facilities/ supplies required	• Immediate access to anaphylaxis medication as appropriate to current NHS Fife procedure for the Management of Anaphylaxis. • Immediate telephone access to GP/Clinician • Access to a BNF • NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) should be followed • Adhere to hand decontamination policy • Access to Immunisation against Infectious Disease (Green Book) Chapter 19 Influenza
Disposal	• Sharps, vials and other vaccine equipment should be disposed of following NHS Fife policies for disposal of sharps and other harmful substances

3. Staff characteristics

Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer the inactivated Influenza vaccine inj. under this PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • physiotherapists, chiropodists/podiatrists currently registered with the Health and Care Professions Council (HCPC) and who hold a recognised qualification in Injection Therapy • dental hygienists and dental therapists currently registered with the General Dental Council
Specialist competencies or qualifications	Persons must only work under this PGD where they are competent to do so All practitioners operating this PGD must demonstrate appropriate knowledge and skills to work under the PGD 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 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 • have undertaken NHS Fife approved anaphylaxis management training • have undertaken NHS Fife approved training in basic life support • must be conversant with key issues in vaccine management (e.g. safe transport, maintaining cold-chain etc) in accordance with NHS Fife Policies • It is essential that the NHS Fife approved PGD e-learning programme is accessed and completed by NHS Fife employed staff • It is the responsibility of the designated authorised staff using this PGD to ensure that treatment with the vaccine detailed in the direction is appropriate. If in any doubt, advice should be sought and recorded before the vaccine is administered <u>Employer</u> 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**
Continued training requirements	• Maintain own professional level of competence and knowledge in this area • Keep up-to-date with information on contraindications, cautions and interactions for all vaccines administered in accordance with this PGD from the BNF, SPC and PIL and refer to a doctor if necessary • Annual update of anaphylaxis management according to NHS Fife Policy • Annual update of training in basic life support • A 2 yearly update of the PGD e-learning programme is essential for NHS Fife employed staff.

4. Referral arrangements/Audit trail

Arrangements for referral to medical advice	• The patient may be referred to a doctor at any stage, if this is necessary, in the professional opinion of the healthcare professional
Records/Audit trail	• Enter in record – date – name of patient – date of birth or CHI no. – name and brand of vaccine – batch number – expiry date – dose/volume – quantity administered – route and site of administration – name of clinician providing treatment – signature / individual log-on details of clinician providing treatment • Record on appropriate form. • Depending on the clinical setting where immunisation is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: – GP practice computer or EMIS, ECS etc. – Individuals GP records or EMIS, ECS etc. – Occupational Health Systems

	– Handheld records (e.g. Red book for children and the Scottish Woman-Held Maternity Record (SWHMR) – Child Health Information Systems/Scottish Immunisation Record – Consent forms/Consultation forms – Neo 360 (in community pharmacy where appropriate)

References/ Resources & comments	• NHS Fife Consent Policy
	• NHS Fife Procedure for the Management of Anaphylaxis
	• NHS Fife Resuscitation Guidelines
	• NHS Fife Safe and Secure Use of Medicines Policy and Procedure (SSUMPP)
	• NMC/RPS Administration of Medicines Guidance Jan 2019
	• 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 available at www.medicines.org.uk
	  • Educational resources for registered professionals produced by National Education for Scotland
	  • All relevant Scottish Government advice including the relevant CMO letter(s)

This Patient Group Direction has been assessed for Equality and Diversity Impact

Appendix 1: Seasonal Influenza Vaccine PGDs 2022-23 - 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 (0.5ml dose)	Latex free Risk of formaldehyde residue	Neomycin[2]
Seqirus	Flucelvax Tetra ®▼ QIVc Cell-based Quadrivalent Influenza Vaccine (Surface Antigen, Inactivated) Seqirus suspension (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
Seqirus	Fluad Tetra ®▼ aQIV 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	≤1 µg (0.5ml dose)	Latex free[2] Risk of formaldehyde residue	Kanamycin[3] Neomycin[3]

Notes

None of the influenza vaccines for the 2022 to 2023 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 **01 August 2022**, 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.

5. Management and monitoring of patient group direction

Patient Group Direction for the administration of

INACTIVATED INFLUENZA VACCINE (INJECTABLE)
By health professionals legally permitted to operate under a PGD
to individuals aged 6 months and upwards
(EXCLUDES LIVE ATTENUATED INTRANASAL VACCINE)

This patient group direction is to be read, agreed to, and signed by all healthcare professionals it applies to.
One signed copy is to be given to each clinician with the original being kept on file by the line manager
One signed copy should be forwarded to the appropriate lead clinician.

Healthcare Professional Agreement

I _____, confirm that I have read and understood the above Patient Group Direction. I confirm that I have the necessary professional registration, competence, and knowledge to apply the Patient Group Direction. I will ensure my competence is updated as necessary. I will have ready access to a copy of the Patient Group Direction in the clinical setting in which supply or administration of the medicine will take place.

I understand that it is the responsibility of the healthcare professional to act in accordance with the GPhC/NMC Guidelines for Professional Practice and Guidelines (or Guidelines,/ Code of Ethics of other Professional body) for the Administration (or Supply) of Medicines and to keep an up to date record of training and competency.

Name of clinician----------

Professional Category----------

Registration No.----------

Name & Contractor code HB
(Pharmacy/Dental/ only) ----------

Please email a copy to Fife.pgd@nhs.scot

Is authorised to give **injectable influenza vaccines (inactivated)** listed under this patient group direction

Place of Work----------

Signature of clinician----------

Date----------

Authorised by:

Name of authorising clinician/manager----------

Signature----------

Date----------

If this PGD is past its review date then the content will remain valid until such time as the PGD review is complete and the new issue published