Patient Group Direction template

Administration of inactivated influenza vaccine

Please note live attenuated intranasal vaccine is not covered by this PGD – separate PGD is available.

Version 1.1 Season 2020-21

Change history

September 2020 – version 1.1

Name of medicine section and Appendix 1 update to reflect current black triangle status of vaccines

August 2020 – version 1.0 developed (now branded as Public Health Scotland)

The following changes from the PGD used in 2019-20 have been made:

- Indication section updated for dates for 2020-21 season
- Updated to include those who live in the same home as individuals falling within the COVID-19 shielding group
- Updated to include social care workers
- Inclusion criteria section updated for dates for 2020-21 season
- Exclusion section updated with updated information in wording related to anaphylactic reaction due to component traces in vaccines
- Name of medicine section updated to reflect vaccines procured for 2020-21 programme
- Route of administration section updated with minor amendments in sections for individuals on stable anticoagulation therapy and individuals with bleeding disorders to align with wording in the Green Book
- Use outwith SPC section updated for dates for 2020-21 season
- References section has been updated

PGD inactivated influenza vaccine

Authorisation

This Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should amend/adapt this PGD template and must ensure that the 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 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 Borders by

Doctor	Dr Tim Patterson	Signature	
Pharmacist	Adrian Mackenzie	Signature	
Nurse	Chris Faldon	Signature	

Approved on behalf of NHS Borders by

Medical Director	Dr Cliff Sharp	Signature	
Director of Pharmacy/Senior Pharmacist	Alison Wilson	Signature	
Clinical Governance Lead	Nicky Berry	Signature	

Date Approved 26/08/2020.

Effective from	01/09/2020	Review Date	31/08/2021

Clinical Situation

Indication	Active immunisation against disease caused by influenza virus in line with Scottish Government seasonal influenza immunisation programme 2020-21.
Inclusion Criteria	Individuals aged 65 years or above on 31st March 2021 Individuals aged six months to 64 years identified in the Scottish Government's seasonal influenza vaccination programme 2020-21 in the following groups; • all those in the clinical risk groups laid out in Annex A of CMO 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 • 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 prisons, young offenders institutions, university halls of residence etc.) • 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. • households of those shielding – those who live in the same home as individuals falling within the COVID-19 shielding group Health care workers who are in direct contact with patients/service users 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. Valid consent has been given to receive the vaccine.
Exclusion Criteria	Children under 6 months. Confirmed anaphylactic reaction to a previous dose of influenza vaccine. 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 SPC for the particular brand. History of confirmed anaphylactic reaction to eggs/egg product or chicken proteins such as ovalbumin where vaccine was produced using eggs. History of severe (i.e. anaphylactic) reaction to latex where vaccine is not latex free. Acute febrile illness – consider postponing immunisation until patient has fully recovered. 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 SPC for the particular brand when administering vaccines. For the centrally procured vaccines: • Adjuvanted TIV is licensed from 65 years • Flucelvax Tetra ▼(cell based QIV) is licensed from age 9 years • Quadrivalent influenza vaccine ▼(Sanofi Pasteur) (egg based QIV) is licensed from 6 months
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	Egg Allergy: Egg-allergic adults and children over age nine years with egg allergy can be given the quadrivalent inactivated egg-free vaccine, Flucelvax Tetra ▼, which is licensed for use in this age group. Adult patients can be immunised in any setting using an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to less than 0.06 micrograms for 0.5 ml dose), excepting those with severe anaphylaxis to egg which has previously required intensive care. Minor Illnesses Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.
Action if Excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given. The risk to the individual of not being immunised must be taken into account. Document in clinical records. In some cases the individual may still be vaccinated using a patient specific direction. Temporary exclusion: In case of postponement due to acute febrile illness, arrange a future date for immunisation.
Action if Patient	Advise individual about the protective effects of the vaccine, the

Declines	risks of infection and complications and the risk of spreading the disease to other members of the public. Give advice on measures to limit the spread of infection. Document advice given and decision reached. In GP practice setting, inform or refer to GP.

Description of Treatment

<table>
<tr><td>Name of Medicine</td><td>Inactivated influenza vaccine marketed in UK 2020-21
https://www.england.nhs.uk/wp-content/uploads/2020/05/national-flu-immunisation-programme-2020-2021.pdf

It is possible this will be updated during the influenza vaccination season

<table>
<tr><th>Age</th><th>Current recommended influenza vaccine for national programme</th></tr>
<tr><td>6 months to less than 2 years</td><td>Offer Sanofi Pasteur Quadrivalent influenza vaccine (egg based QIV) ▼

Note Fluenz Tetra (LAIV), Flucelvax Tetra▼ (Cell based QIV). Adjuvanted TIV are not licensed in this age group</td></tr>
<tr><td>2 years to under 18 years (unsuitable for LAIV)</td><td>Offer a suitable quadrivalent inactivated influenza vaccine (QIV)

Note Sanofi Pasteur Quadrivalent influenza vaccine (egg based QIV) ▼ is licensed from 6 months, Flucelvax Tetra▼ (Cell based QIV) is licensed from 9 years of age). Adjuvanted TIV is not licensed in this age group</td></tr>
<tr><td>18 years to under 65 years</td><td>Offer Flucelvax Tetra▼ (Cell based QIV) vaccine

Note Fluenz Tetra (LAIV) and Adjuvanted TIV are not licensed in this age group</td></tr>
<tr><td>65 years and over (including those 64 year olds who are 65 years old by 31st March 2020</td><td>Offer Adjuvanted TIV</td></tr>
<tr><td>Health and social care staff</td><td>Offer Flucelvax Tetra▼ (Cell based QIV) vaccine</td></tr>
</table>

(Fluenz Tetra (LAIV) is not covered by this PGD).</td></tr>
<tr><td>Form/Strength</td><td>Suspension for injection.</td></tr>
<tr><td>Route of administration</td><td>Intramuscular injection.</td></tr>
</table>

	Preferred site for children older than 12 months or adults is deltoid area of upper arm. Preferred site for infants is anterolateral thigh. Adjuvanted TIV or Flucelvax Tetra▼ (Cell based QIV) must only be administered via the intramuscular route. Due to the presence of adjuvant (MF59C), Adjuvanted TIV should be administered intramuscularly using a 25mm needle. 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 Egg-based QIV such as Quadrivalent influenza vaccine ▼ (Sanofi Pasteur) should be administered via the intramuscular route except where there is a bleeding disorder when the deep subcutaneous route should be used to reduce the risk of bleeding.
Dosage	Single dose of 0.5ml
Frequency	Children aged 6 months to less than 9 years who have not received influenza vaccine before should receive a second dose of vaccine at least 4 weeks later
Duration of treatment	Not applicable.
Maximum or minimum treatment period	Not applicable.
Quantity to supply/administer	Not applicable.
▼ additional monitoring	Yes, Flucelvax Tetra▼ (Cell based QIV), Quadrivalent influenza vaccine▼ (Sanofi Pasteur)
Legal Category	POM – prescription only medicine.
Is the use out with the SPC	Adjuvanted TIV 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 31st March 2021 in

	accordance with the Scottish Government seasonal influenza immunisation programme 2020-21. 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 HPS 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	Before each dose is administered the vaccine should be shaken well. Inactivated influenza vaccine can be given at the same time as other 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 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 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.

Reporting procedure for adverse reactions	Suspected adverse reactions should be reported via the Yellow Card Scheme using the yellow card system on http://yellowcard.mhra.gov.uk/. Any serious adverse reaction to the vaccine should be documented in an individual's record. GP should also be informed.

Advice to Patient/carer including written information	Marketing authorisation holder's patient information leaflet (PIL) provided with vaccine. Inform of possible side effects and their management. Give advice regarding normal reaction to the injection e.g. sore arm is possible. In children, give advice on monitoring of temperature and use of measures to lower temperature (such as giving paracetamol). Advise individual to seek medical advice in case of severe adverse reaction. 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	Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection Access to telephone**.**

Characteristics of staff authorised under the PGD

Professional qualifications	Those registered health care professionals that are listed and approved in legislation as able to operate under Patient Group Directions.
Specialist competencies or qualifications	Approved by the organisation as competent: • to undertake immunisation and discuss issues related to immunisation, • to assess the person's capacity to understand the nature and purpose of the immunisation in order to give or refuse consent, • to work with this patient group direction, • in the recognition and management of anaphylaxis,
Continuing education and training	The practitioner must be familiar with the marketing authorisation holder's SPC for all vaccines administered in accordance with this PGD. It is the responsibility of the individual to keep up to date with all aspects of immunisation and in the recognition and management of anaphylaxis.

Audit trail

Record/Audit Trail	The approved practitioner must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. The information relating to immunisation of each individual must include as a minimum: • Patient's name and date of birth, • Dose, • Site and route of injection, • Name of vaccine, brand, batch number and expiry date of vaccine, • Date given and by whom (name and signature). All records must be clear and legible and, ideally, in an easily retrievable format. 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, • Individuals GP records, • 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.
Additional references	Practitioners operating the PGD must be familiar with: Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book Immunisation against Infectious Disease [Green Book] chapter 19 https://www.gov.uk/government/publications/influenza-the-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 https://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/seasonal-flu.aspx All relevant Scottish Government advice including the relevant CMO letter(s) Professional Guidance on the Administration of Medicines in Healthcare Settings 2019 https://www.rpharms.com/Portals/0/RPS document library/Open access/Professional standards/SSHM Admin/Admin Meds prof guidance.pdf/ver=2019-01-23-145026-567 Professional Guidance on the Safe and Secure Handling of Medicines https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines

PGD for administration of influenza vaccine (inactivated) – Authorisation

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.

Note to Authorising Managers

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.

I have read and understood the Patient Group Direction. I agree to administer influenza vaccine (inactivated) only in accordance with this PGD.

Name of Professional	**Signature**	**Date**

I agree that the professionals listed above are authorised to supply/administer medicines in accordance with this PGD to patients cared for in this service area.

Lead Clinician for the service area (Doctor)		
Name:	Signature:	Date:

Appendix 1. Seasonal Influenza Vaccine PGDs 2020-21 - UK Licensed Influenza Vaccines

1. 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 Gelatin (porcine) Formaldehyde free	Gentamicin[2]
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]
Sequirus	Flucelvax Tetra ®▼ **QIVc**	Cell grown quadrivalent influenza vaccine surface antigen inactivated prepared in cell cultures	From 9 years	n/a egg free	Latex free[1] Formaldehyde free	n/a
	aTIV	Adjuvanted trivalent influenza vaccine surface antigen, inactivated Adjuvanted with MF59C.1	From 65years	≤0.2 µg	Latex free[1] Risk of formaldehyde residue	Kanamycin[2] Neomycin[2]
GSK	Fluarix Tetra® **QIVe**	Standard egg grown quadrivalent influenza vaccine split virion inactivated	From 6 months	≤0.05 µg	Latex free Risk of formaldehyde residue	Gentamicin[2]
Mylan	Influvac sub-unit Tetra®▼ **QIVe**	Standard egg grown quadrivalent influenza vaccine surface antigen inactivated	From 3 years	≤ 0.1 µg	Latex free Risk of formaldehyde residue	Gentamicin[2]

None of the influenza vaccines for the 2020-21 season contain thiomersal as an added preservative.

1. 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 may contain 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.

2. 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 4 August 2020, however, these may be subject to change in manufacturing practice at any time.

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