

Seasonal Influenza Vaccine (TRIVALENT inactivated) 2018-19

For individuals 65 to 74 years of age

(N.B. Live Attenuated Intranasal Vaccine (LAIV ▼), Adjuvanted Inactivated Trivalent Vaccine (Fluad® ▼) and Inactivated Quadrivalent Vaccines are not covered by this PGD)

GG&C PGD ref no: 2018/1611

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

Clinical Condition

Indication:	Active immunisation against disease caused by influenza virus in line with Scottish Government Health Directorate seasonal influenza immunisation programme 2018-19.
Inclusion criteria:	Individuals identified in Scottish Government's seasonal influenza vaccination programme 2018-19 in the following groups (with reference to the latest iteration of the CMO letter at http://www.sehd.scot.nhs.uk/); All patients aged 65 years up to and including 74 years of age.
Exclusion criteria:	<ul style="list-style-type: none"> • Individuals 64 years old and younger (refer to Quadrivalent and LAIV PGDs) • Adults 75 years and over (refer to Fluad▼® PGD) • Confirmed anaphylactic hypersensitivity to egg products • Acute febrile illness or fever, immunisation should be postponed until fully recovered • Anaphylactic reaction to a previous dose or any component of the vaccine which may include formaldehyde, gentamicin, neomycin, kanamycin, nonoxynol 9, polymixin B and polysorbate 80. N.B. this is not a comprehensive list, check SPC to exclude specific substances known to cause allergy to patient. • Evolving neurological condition, immunisation should be deferred until resolved or stabilised • History of severe (i.e. anaphylactic) reaction to latex where vaccine is not latex free. (Refer to Appendix 1.) • Non consent
Cautions/Need for further advice/Circumstances when further advice should be sought from the doctor:	<ul style="list-style-type: none"> • Can be administered simultaneously with other vaccines. • Different injectable vaccines should always be given at different injection sites. • Known bleeding disorder administer subcutaneously

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Action if patient declines or is excluded:	<ul style="list-style-type: none"> Refer to relevant clinician e.g. GP, Public Health Consultant. If declined advise regarding protective effect of immunisation and potential disease complications. Document advice given and refer to relevant clinician if appropriate.
Referral arrangements for further advice / cautions:	As above

Drug Details

Name, form & strength of medicine:

Supplier	Name of product	Vaccine type	Age indications	Recommended age group for programmes
BGP products (Mylan)	Influvac®	Trivalent Inactivated	From 6 months	65 years up to and including 74 years ¹
	Influenza Vaccine			
Pfizer	Influenza Vaccine	Trivalent Inactivated	From 9 years ²	65 years up to and including 74 years
	Enzira®			

1. Adjuvanted inactivated trivalent vaccine (Fluad® ▼) is 1st choice for individuals 75 years of age and over. This is covered by a different PGD

2. Age indications and exclusions for use of Inactivated Influenza Vaccine (Pfizer) are based on Green book recommendations rather than the licensed indication which states 5 years.

3. N.B. LAIV ▼ is 1st choice for individuals 2 years up to and including 17 years of age, Quadrivalent inactivated seasonal influenza vaccine is 2nd choice. These vaccines are covered by different PGDs

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	(Appendix 1 details ovalbumin content and potential for latex and aminoglycoside allergy.)
Route/Method of administration:	Intramuscular Deep subcutaneous injection for individuals with a bleeding disorder (caution possibility of reduced immunogenicity with this route)
Dosage (include maximum dose if appropriate):	0.5ml
Frequency:	One dose
Duration of treatment:	n/a
Maximum or minimum treatment period:	n/a
Quantity to supply/administer:	0.5ml
Supply, Administer or Both:	Administer only
▼ Additional Monitoring:*	No
Legal Category:	POM
Is the use outwith the SPC:**	No
Storage requirements:	Store between 2°C-8°C in locked storage. NHS GG&C Vaccine Ordering, Storage and Handling Guidelines should be observed http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/PoliciesProcedures/GGCClinicalGuidelines/Pages/home_page.aspx Vaccine storage history e.g. temperature charts must be checked and deemed satisfactory before administration to patient.
Warnings including possible adverse reactions and management of these:	Please refer to current BNF, eBNF http://www.bnf.org/bnf/ or SPC at http://emc.medicines.org.uk/ for full details Use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on their use are available at the back of the BNF or online at http://yellowcard.gov.uk/
Advice to	Explain treatment and course of action.

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patient/carer including written information provided:	Give patient a copy of any relevant patient information leaflet if available. PIL available at http://emc.medicines.org.uk/ Refer patient to 'Immunisation Scotland' website http://www.immunisationscotland.org.uk/
Monitoring (if applicable):	n/a
Follow up:	See advice to patient/carer

* The black triangle symbol (▼) identifies newly licensed medicines that are monitored intensively by the MHRA/CSM ** Summary of Product Characteristics

Staff Characteristics

Professional qualifications:	Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions and have current registration.
Specialist competencies or qualifications:	Has undertaken appropriate training and competence to undertake immunisation including recognition and treatment of anaphylaxis. Has undertaken appropriate training for working under PGDs for the supply and administration of medicines
Continuing education & training:	All individuals working under the direction will be expected to maintain their competence as specified in hospital policies and Professional Council guidelines. The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development in all aspects of immunisation including recognition and treatment of anaphylaxis.

Referral Arrangements and Audit Trail

Referral arrangements	Any prolonged reaction, whether mild or severe must be reported to an appropriate clinician for the department administering vaccination.
Records/audit trail:	Patient's name, address, date of birth and consent given; Contact details of GP (if registered); Dose, form administered and batch details. Advice given to patient (including side effects); Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment; Details of any adverse drug reaction and actions taken including

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documentation in the patient's medical record;
Referral arrangements (including self-care)
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

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References/Resources and comments:

Notes:

SPC – Summary of Product Characteristics

<http://emc.medicines.org.uk/>

BNF – British National Formulary

<https://www.medicinescomplete.com/about/subscribe.htm>

NMC (2015) Standards for Medicines Management

<https://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/>

NMC (2015) The NMC Code of Professional Conduct: standards for conduct, performance and ethics

<https://www.nmc.org.uk/standards/code/>

Immunisation against Infectious Diseases (2006). DOH (green book) always refer to on-line version

<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

NHS Health Scotland website

<http://www.healthscotland.com/topics/health/immunisation/index.aspx>

SEHD circulars <http://www.sehd.scot.nhs.uk/>

NHS GG&C Immunisation Best Practice Guideline

NHS GG&C Vaccine Ordering Storage and Handling Guidelines

http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/Policies/Procedures/GGCClinicalGuidelines/Pages/home_page.aspx

[X](#)

Health Protection Scotland Immunisation and Vaccine Preventable Diseases website NHS HealthScotland website

<http://www.hps.scot.nhs.uk/immvax/guidelines.aspx>
<http://www.healthscotland.com/topics/health/immunisation/index.aspx>

NHS Inform www.nhsinform.scot/immunisation

Heinonen S, Silvennoinen H, Lehtinen P et al. (2011) Effectiveness of inactivated influenza vaccine in children aged 9 months to 3 years: an observational cohort study. *Lancet Infect Dis.* 11: 23-29.

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This Patient Group Direction must be agreed to and signed by all healthcare professionals involved in its use. The original signed copy will be held at PPSU, Floor 2, West Glasgow ACH, Dalnair Street, Glasgow. The PGD must be easily accessible in the clinical setting.

Organisation: NHS Greater Glasgow & Clyde

Professionals drawing up PGD/Authors

		Designation and Contact Details
Name: Dr Syed Ahmed  Signature: _____ Date: 17/08/2018		Designation: Consultant in Public Health Medicine Public Health Protection Unit Westhouse, NHS GG&C E-mail address: syed.ahmed@ggc.scot.nhs.uk
Name: *Val Reilly  Signature: _____ Date: 17/08/2018		Designation: Public Health Pharmacist Pharmaceutical Public Health Westhouse, NHS GG&C E-mail address: val.reilly@ggc.scot.nhs.uk
Name: Hilda Crookshanks  Signature: _____ Date: 17/08/2018		Designation: Health Protection Nurse Specialist Public Health Protection Unit West House, NHSGGC E-mail address: Hilda.crookshanks@ggc.scot.nhs.uk

* **Lead Author**

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AUTHORISATION:

NHS GG&C PGD & Non-medical Prescribing Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	Signature:	Date:
Dr Craig Harrow		21/08/2018

Lead of the professional group to which this PGD refers:		
Professional Nurse Advisor, Primary Care in BLOCK CAPITALS	Signature:	Date:
Karen Jarvis		21/08/2018

Pharmacist representative of PGD & Non-Medical Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	Signature:	Date:
Elaine Paton		21/08/2018

Antimicrobial use

If the PGD relates to an antimicrobial agent, the use must be supported by the NHS GG&C Antimicrobial Management Team (AMT). A member of this team must sign the PGD on behalf of the AMT.

Microbiology approval	Name:	Designation:
	Signature:	Date:
	(on behalf of NHS GG&C AMT)	

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Local Authorisation:

Service Area for which PGD is applicable:

I authorise the 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:	Designation:	Date:

E-Mail contact address:

I agree that only fully competent, qualified and trained professionals are authorised to operate under the PGD. Records of nominated individuals will be kept for audit purposes.

Name (Lead Professional):	Signature:	Designation:	Date:

E-Mail contact address:

Description of Audit arrangements:

Frequency of checks: (Generally annually)	Names of auditor(s):

**PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR
 ACCOUNTABILITY.**

**It is the responsibility of each professional to practice only within the bounds of their own
 competence and in accordance with their own Code of Professional Conduct.**

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 acknowledge that it is a legal document and agree to supply/administer this medicine only in accordance with this PGD.

Name of Professional	Signature	Date

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