Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older
(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

GG&C PGD ref no: 2018/1603

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 seasonal influenza immunisation programme 2018-19.
Inclusion criteria:	Individuals aged 75 years and above. (N.B. The vaccine Summary of Product Characteristics (SPC) states that the vaccine may be used for individuals 65 years and older. However, use limited to individuals 75 years and older is specified by the national programme)
Exclusion criteria:	• Non consent • Individuals <75 years • Evolving neurological condition, immunisation should be deferred until resolved or stabilised • History of severe reaction (i.e. anaphylactic reaction) to latex where vaccine is not latex free. • Acute illness or fever, immunisation should be postponed until fully recovered. • Confirmed anaphylactic reaction to a previous dose of influenza vaccine. • Confirmed anaphylactic reaction to any component of the vaccine which may include neomycin, kanamycin, formaldehyde and other excipients – practitioners must check the marketing authorisation holder's SPC. • Confirmed anaphylactic reaction to MFC59C.1 adjuvant. • Confirmed anaphylactic reaction to eggs/egg product or chicken proteins such as ovalbumin. • Individuals on warfarin who are not up to date with their scheduled INR testing and/or whose latest INR is not below the upper threshold of their therapeutic range • Individuals on anticoagulant therapy which is not stable

Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older
(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

Cautions/Need for further advice/Circumstances when further advice should be sought from the prescriber:	Known bleeding disorder or on anticoagulants 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. 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. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy
Action if patient declines or is excluded:	Refer to appropriate clinician e.g. GP, Travel Health Consultant, Sexual Health, GUM or ID Consultant. If declined give advice regarding protective effect of immunisation and potential disease complications. Document advice given and refer to appropriate clinician.
Referral arrangements for further advice / cautions:	As above

Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older
(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

Drug Details

Name, form & strength of medicine:	Adjuvanted trivalent influenza vaccine (inactivated) Fluad® Suspension for injection (N.B. Live attenuated intranasal vaccine (LAIV), Quadrivalent influenza vaccine (inactivated and Trivalent influenza vaccine (inactivated) are not covered by this PGD).
Route/Method of administration:	**Intramuscular only.** Due to the presence of adjuvant (MF59C), Fluad® should be administered intramuscularly using a 25mm needle. For patients on anticoagulants or with a bleeding disorder: following administration, firm pressure should be applied to the site (without rubbing) for at least 2 minutes. Inform the individual/carer of the risk of haematoma from the injection
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:	One dose
Supply, Administer or Both:	Administer only
▼Additional Monitoring:*	Yes
Legal Category:	POM
Is the use outwith the SPC:**	No
Storage requirements:	Store between 2^0C-8^0C 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.

*** The black triangle symbol has now been replaced by European "additional monitoring" (▼)**
**** Summary of Product Characteristics**

Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older
(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

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. Please refer to current BNF www.medicinescomplete.com or SPC at http://emc.medicines.org.uk/ for full details Use the Yellow Card System to report adverse drug reactions directly to the CMS. Yellow Cards and guidance on their use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/
Advice to patient/carer including written information provided:	Explain treatment and course of action. Give patient a copy of relevant patient information leaflet, if appropriate. If condition worsens or symptoms persist then seek further medical advice
Monitoring (if applicable):	
Follow up:	See advice to patient/carer

Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older
(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

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 health care professionals working under the direction will be expected to maintain their competence as specified in hospital, local and national policies e.g. Nursing & Midwifery 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 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 (e.g. Red book for children and the Scottish Woman-Held Maternity Record (SWHMR) • Child Health Information Systems • Consent forms.
References/Reso	SPC – Summary of Product Characteristics

Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older
(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

urces and comments:	http://emc.medicines.org.uk/ BNF – British National Formulary www.medicinescomplete.com 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/ 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/Clinical%20Guidelines/Pages/default.aspx Immunisation against Infectious Diseases (2006). DOH (green book) always refer to on-line version NHS Health Scotland website https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book http://www.healthscotland.com/topics/health/immunisation/index.aspx Health Protection Scotland Immunisation and Vaccine Preventable Diseases website http://www.hps.scot.nhs.uk/immvax/guidelines.aspx NHS Inform www.nhsinform.scot/immunisation

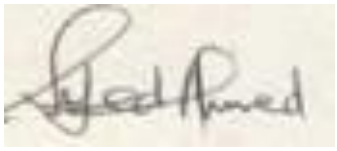
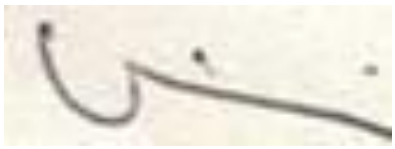
Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older
(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

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, 2nd Floor Main Building, West Glasgow ACH. 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: 18/07/2018	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: 18/07/2018	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: 18/07/2018	Designation: Health Protection Nurse Specialist Public Health Protection Unit West House, NHSGGC E-mail address: Hilda.crookshanks@ggc.scot.nhs.uk

*** Lead Author**

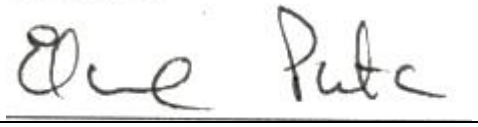
Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older
(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

AUTHORISATION:

NHSGG&C PGD Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	**Signature:**	**Date:**
Dr Craig Harrow		**18/07/2018**

NHSGG&C PGD Sub-Committee of ADTC		
Professional Nurse Advisor, Primary Care in BLOCK CAPITALS	**Signature:**	**Date:**
Karen Jarvis		**18/07/2018**

Pharmacist representative of PGD Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	**Signature:**	**Date:**
Elaine Paton		**18/07/2018**

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)	

Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older

(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

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**

Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older
(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

Patient Group Direction Audit Form
Form for the audit of compliance with PGD or PGDs

To ensure best practice all PGDs should be audited on a 6 monthly basis.

Name and post of Designated Lead person within each practice/clinic base:			
Location/Clinic Base: **Date of audit:**			
Tick as appropriate. If 'no', state action required	**Y**	**N**	**Action**
Is the PGD or PGDs utilised within the clinical area?			
Has the PGD or PGDs been reviewed within the 2 year limit?			
Do the managers listed on the PGD or PGDs hold a current list of authorised staff?			
Are all staff authorised to work under the PGD or PGDs members of one of the health professions listed in the PGD?			
Do all staff meet the training requirements identified within the PGD?			
Are you confident that all medicines supplied or administered under the PGD or PGDs are stored according to the PGD where this is specified?			
Do the staff working under the PGD or PGDs have a copy of the PGD which has governance sign off and is in date and, available for reference at the time of consultation?			
Where the medicine requires refrigeration. (Delete if not required).			
Is there a designated person responsible for ensuring that the cold chain is maintained?			
Is there a record that the fridge temperature has been monitored to required levels?			
If there is regular and sustained reliance on PGDs for service provision has a Non Medical Prescribing approach been considered as an alternative? (Please note reasons for either a Y/N response).			

Name:	Date of audit:

Keep copies of completed audits alongside your PGD for local reference.

Adjuvanted trivalent influenza vaccine (inactivated) (Fluad®)

For individuals 75 years and older
(N.B. Live Attenuated Intranasal Vaccine (LAIV▼) and inactivated trivalent and quadrivalent vaccines are not covered by this PGD)

Please retain at local level and ensure audit forms are readily available as they may be required for clinical governance audit purposes.