

Seasonal Influenza Vaccine (QUADRIVALENT inactivated) 2018-19

**For individuals 6 months to 64 years and Health and Social Care Workers
 (N.B. Live Attenuated Intranasal Vaccine (LAIV ▼), Adjuvanted Inactivated
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 covered by this PGD)**

GG&C PGD ref no: 2018/1612

**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:	<p>Individuals identified in Scottish Government's seasonal influenza vaccination programme 2018-19 in the following groups;</p> <ul style="list-style-type: none"> • all those aged six months and over in the clinical risk groups laid out in the latest iteration of the Chief Medical Officer letter on Seasonal Influenza Vaccination Programme at http://www.sehd.scot.nhs.uk/ • Those individuals who, in the opinion of their general practitioner are at risk of an influenza infection exacerbating their disease symptoms • pregnant women at any stage of pregnancy (first, second or third trimester) • 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. • Health and social care staff • Individuals for whom LAIV ▼ is contraindicated e.g. pregnancy or unacceptable due to porcine gelatin content.

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Exclusion criteria:	<ul style="list-style-type: none"> • Children under 6 months • Adults aged 75 years and over <p>Age exclusions detailed in the latest iteration of the Chief Medical Officer letter on Seasonal Influenza Vaccination Programme at http://www.sehd.scot.nhs.uk/ and the Green Book.</p> <ul style="list-style-type: none"> • Children <18 years (Tetra MYL ▼[®], Quadrivalent Influenza vaccine- Mylan) • 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
Action if patient declines or is excluded:	<ul style="list-style-type: none"> • Refer to relevant clinician e.g. GP, Public Health Consultant. <p>If declined advise regarding protective effect of immunisation and potential disease complications. Document advice given and refer to relevant clinician if appropriate.</p>
Referral arrangements for further advice / cautions:	As above

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Drug Details

**Name, form & strength
of medicine:**

Supplier	Name of product	Vaccine type	Age indications	Recommended age group for programme
BGP products (Mylan)	Tetra MYL® ▼ ¹	Quadrivalent Inactivated	From 18 years	18 years up to and including 64 years Health and Social Care Workers >18 years
Sanofi Pasteur /Aventis vaccines	Quadrivalent Influenza vaccine ▼ (split virion)*	Quadrivalent Inactivated	From 6 months	6 months up to and including 64 years ² Health and Social Care Workers

1. Tetra MYL Quadrivalent inactivated vaccine is **not** recommended for individuals under 18 years of age.
 2. Trivalent inactivated vaccine is 1st choice for individuals 65 up to and including 74 years of age. This is covered by a different PGD
 3. LAIV ▼ is 1st choice for individuals 2 years up to and including 17 years of age. This is covered by a different PGD
- (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 or two doses – depending on history of influenza vaccination and clinical status
Children aged less than 9 years who are in a clinical at risk group who have not received influenza vaccine before should receive two doses of seasonal influenza vaccine with the second dose at least 4 weeks after the first. Inactivated influenza vaccine can be given if

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LAIV ▼ is not available for the second dose e.g. due to batch expiry

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:*	Yes
Legal Category:	POM
Is the use outwith the SPC:**	Yes SPCs advise limited data for use and efficacy in first trimester of pregnancy. However use in both groups is within current JCVI recommendations described in the Green Book.
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 patient/carer including written information provided:	Explain treatment and course of action. 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

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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:	<p>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)</p> <p>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:</p> <ul style="list-style-type: none"> • 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.

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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/PoliciesProcedures/GGCClinicalGuidelines/Pages/home_page.aspx

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, Queens Park House, Victoria Infirmary. 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**

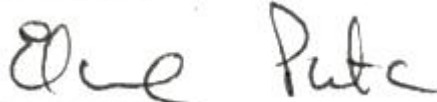
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AUTHORISATION:

NHSGG&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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