North Yorkshire County Council

Health and Adult Services

Patient Group Direction (PGD) for the Administration of

INFLUENZA (SEASONAL FLU) VACCINES

by Registered & Accredited Pharmacists to staff working for North Yorkshire County Council (NYCC) Health and Adult Services (HAS) Accessing the NYCC Influenza Staff Vaccination Service from Commissioned Community Pharmacies within North Yorkshire County and City of York

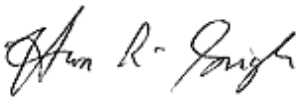
YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

Direction Number: - **NYCC 2018/CP03**

Valid from: 22nd October 2018

Review date: 1st June 2020

Expiry date: 30th September 2020

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Public Health Medicines Adviser (Lead Author) (Medicines Optimisation Pharmacist, North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		11/10/18
Medical Director (North of England Commissioning Support)	**Dr James Gossow** *(Senior Doctor)*		17/10/18
Community Pharmacist (Vice Chair, North Yorkshire LPC)	**Tracey Chambers** *(Senior Pharmacist)*		11/10/18

Development also includes contribution from:
Carly Walker (Health Improvement Manager, Public Health – HAS, North Yorkshire County Council)

This PGD has been approved for use in North Yorkshire County Council by:			
Title	Name	Signature	Date
Director of Public Health (North Yorkshire County Council Public Health)	**Dr Lincoln Sargeant** *(Authorising body Governance Authorisation)*		22/10/18

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

- Patients identified as requiring influenza vaccination or requesting vaccination who meet inclusion criteria.

Objectives of care

- To reduce morbidity and mortality from influenza.

Inclusion criteria

(Only use those criteria that are specific to your authorised role & competence. Ensure appropriate consent has been obtained or a best interest decision is in place before commencing vaccination.

Eligible individuals are those falling into the following group:

- NYCC Health and Adult Services (HAS) employed staff who are 18 years old and over presenting a voucher that has been signed by their manager.

  NB. For NYCC staff members who also fall into one of the NHS eligible groups* for Flu Vaccination please see exclusions for eligible individuals. These individuals should access the national NHS Flu vaccination programme.

(* For full NHS eligibility details refer to the Community pharmacy seasonal influenza vaccination advanced service (August 2018), NHS England Publications Gateway Reference: 08291, Annex A). https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service/

N.B For the avoidance of doubt, this PGD specifically does not cover patients, residents or service users and only applies to employed staff of North Yorkshire County Council.

Exclusion criteria (please also refer to current SPC and latest BNF)

Clients fulfilling one or more of the following criteria are excluded from supply under this PGD: -

- No valid consent /best interest decision in place.
- NYCC HAS staff members who fall into one of the eligible groups as defined in Annex A of the NHS England Publication, "Community pharmacy seasonal influenza vaccination advanced service (August 2018)" Gateway Reference: 08291. (These individuals cannot be vaccinated under this PGD, but should access vaccination under the national NHS Flu vaccination programme).
- Patient is acutely unwell/suffering from acute severe febrile illness. In this case vaccination should be postponed until patient has recovered. (Without fever or systemic upset the presence of minor infections are not a contra-indication for immunisation and so are not reasons to postpone immunisation).
- Confirmed anaphylactic reaction to a previous dose of an influenza vaccine.
- Confirmed anaphylactic reaction to any component, ingredient, or excipient of the vaccine (other than ovalbumin). See precautions.
- Confirmed severe anaphylaxis to egg which has previously required intensive care (refer to specialist for immunisation in hospital). Please also refer to precautions section - egg allergy.
- Hypersensitivity to formaldehyde & chicken protein or any excipient or residue listed within the vaccine's SPC or product information. (See also Precautions section).
- Have already received a dose of an influenza vaccine for the current season

Refer to current Summary of Product Characteristics (SPC) / BNF (current on-line version)/ latest BNF for full list of details

Cautions/Precautions

- Hypersensitivity reactions to previous dose of vaccine or component, ingredient or excipient of vaccine:
  - **NB**. "Local adverse reactions that generally start within a few hours of the injection are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens"
- Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration).
- Syncope (fainting) can occur following, or even before, any vaccination 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.
- **Patients with egg allergy**
  - Adults with a history of severe anaphylaxis to egg, which has previously required intensive care, should be referred to specialists for immunisation in hospital.
  - With the exception of those individuals with severe anaphylaxis to egg which has previously required intensive care (see Criteria for exclusion), individuals with less severe egg allergy can be immunised in any setting using an inactivated influenza vaccine with an ovalbumin content of less than 0.12mcg/ml **(equivalent to 0.06mcg per 0.5ml dose**). Refer to Section 2 (Table 1) for products with low ovalbumin content.

Action if excluded

- Ensure all actions/decisions are documented.
- If postponement due to acute illness, arrange a future date for immunisation
- Individuals with confirmed severe anaphylaxis to egg, which has previously required intensive care, refer to GP.
- Ensure all actions/decisions are documented. If treatment is refused, this must be recorded on PharmOutcomes.

Arrangements for referral to medical advice

- Patients on immunosuppressive treatment or with immunodeficiency – refer to GP
- Patients with hypersensitivities or where inclusion or exclusions are not conclusive – refer to GP
- Those with a confirmed severe anaphylaxis to egg or those with egg allergy + severe uncontrolled asthma (refer to GP)

Action if patient declines treatment (offer to assist the patient in this process)

- Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration.
- Ensure patient fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications.
- Give advice about the disease, how to recognise it and action required if suspected.
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate.
- Record the refusal in the clinical record and document all other actions taken.

2. Description of treatment

Name, strength & formulation of drug

Inactivated Influenza Vaccine 0.5ml in a Pre-filled Syringe (PFS); i.e.

- **Inactivated quadrivalent influenza vaccine (QIV)**

(NB. Very low ovalbumin content vaccines (<0.12mcg/ml – equivalent to <0.06mcg for a 0.5ml dose) may be used safely in individuals with egg allergy, except in those with severe anaphylaxis (Also see precautions section)).

Table 1 - Influenza vaccines available for 2018/19 national influenza immunisation programme are: -

Supplier	Name of product	Vaccine Type	Age indications	Ovalbumin content (µg/ dose)
GlaxoSmithKline	**Fluarix ™ Tetra ▼**	Split virion inactivated virus (quadrivalent)	**From 6 months**	≤0.1mcg/ml ≤ 0.05mcg / 0.5ml dose
MASTA	**Quadrivalent Influenza Vaccine (Split Virion, inactivated) ▼**	Split virion inactivated virus	**From 6 months**	≤0.1mcg/ml ≤ 0.05mcg / 0.5ml dose
Mylan, (BGP Products)	**Quadrivalent Influenza vaccine Tetra MYL ▼** **Quadrivalent Influvac ® sub-unit Tetra ▼**	Influenza virus surface antigen (inactivated)	**From 18 years**	0.2mcg/ml 0.1/0.5ml dose
Sanofi Pasteur	**Quadrivalent Influenza Vaccine (split virion, inactivated) ▼**	Split virion inactivated virus	**From 6 months**	≤0.1mcg/ml ≤ 0.05mcg / 0.5ml dose

▼ Black Triangle Drug (under intensive surveillance). (Please also refer to the relevant SPCs & Green Book Chapter 19 - Influenza).

None of the influenza vaccines for 2018/19 season contain thiomersal as an added preservative

Legal Status:

POM – Prescription Only Medicines

Vaccine should be stored according to the conditions detailed in their SPC. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.

Refer to products' SPCs at www.medicines.org.uk for more information.

Dosage /Dose range and frequency

18 to 64 years old:

Offer 1 single 0.5ml dose of a suitable QIV for the current annual flu season

(Excludes those 64 year olds becoming age 65 years by 31st March 2019, as they will be eligible under the national flu programme). See also Special considerations/Additional Information section

Frequency of Administration

Annual - (see also section on dose)

Route/Method

- **Inactivated influenza vaccines** given by **Intramuscular injection (IM)** should be given preferably into the upper arm or anterolateral thigh (depending on age). Only use deep subcutaneous route for patients with bleeding disorders, (or administer as per SPC).
- 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 (equal to 23 gauge or finer calibre) 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.
- Other vaccines can be given at the same time as influenza vaccine. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, 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 was given should be noted in the individual's records.
- Shake vaccine before administration. Inspect visually prior to administration and ensure appearance is consistent with the description in the SPC for the vaccine being administered.

The SPCs provide further guidance on administration and are available from the eMC website: www.medicines.org.uk

Maximum dose & number of treatments

Maximum dose: **0.5ml** (all inactivated vaccines)

Maximum number of vaccinations: **Dosage** is **1 Single Dose**

(Please see Dosage/Dose range section above. Refer to manufacturer's SPC for exact details and Green Book Chapter 19)

Follow up treatment/action

As above. See also current PHE Green Book recommendations, Chapter 19, pages 16-18.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/456568/2904394_Green_Book_Chapter_19_v10_0.pdf

3. Further Aspects of Treatment

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See Manufacturers SPC for full details / Green Book chapter 19

Potential Adverse Effects/Reactions: -

	Intramuscular Inactivated Influenza Vaccines (various brands)
Very Common & Common Reactions	Injection site pain, swelling and redness, and induration.* Low grade fever, shivering, fatigue, headache, myalgia, arthralgia*. Malaise within 48hours post vaccination. (NB. Arthralgia is rare with quadrivalent influenz vaccine (split virion). *(These reactions usually disappear within 1-2 days without treatment).
Uncommon Effects	See Individual SPC's
Rarely	Anaphylaxis, neuralgia, convulsions. Transient thrombocytopenia. Paraesthesia, vasculitis with transient renal involvement and neurological disorders such as encephalomyelitis.

This list is not exhaustive. See BNF and manufacturers Summary of Product Characteristics (SPC) for details of all interactions, potential adverse reactions and relative occurrence.

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction. All suspected ADR's occurring in children should be reported. Please refer to www.mhra.gov.uk/yellowcard and Green Book- chapter 9.
- Client to report any suspected ADRs believed to be associated with the vaccination to a Healthcare Professional or directly using the Yellow Card system.

Clients and Healthcare Professionals can log ADRs directly via the MHRA website (http://yellowcard.mhra.gov.uk/) or call freephone 0808 100 3352 (10am to 2pm Monday-Friday only).

Please refer to current SPC "special warnings & special precautions for use" section for full details & relevant online chapters of the Green Book.

Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- **Advice on management including anaphylaxis**: - Chapter 8 of the Green Book provides detailed advice on managing Adverse Effects Following Immunisation (AEFIs) e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor if appropriate. **Please be aware of Resuscitation Council Guideline changes (Oct. 2015)**

Please refer to current SPC "special warnings & special precautions for use" section for full details & relevant online chapters of the Green Book.

Records

All details to be recorded on PharmOutcomes as set out in the preferred provider contract with NYCC and be retained according to local, legal and professional obligations. A local record should also be retained by the pharmacy.

In all cases manual or computerised records and data collection should include: -

- Confirmation that consent has been obtained;
- Reason vaccination required;
- Date of administration;
- Patient's name and date of birth;
- Dose, site and route of injection;
- Brand name, batch number & expiry date of vaccine;
- Confirmation that there are no contraindications;
- Whom administered by & signature of vaccinator (if not recorded on computer).
- That side effects have been discussed; Support literature given (if applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.
- It is important that vaccinations given at community pharmacies are recorded in a timely manner. A record of the vaccination should be returned to the individual's GP practice to allow records to be made and avoid duplicate vaccination.

Special Considerations / Additional Information

- Vaccines should be allowed to reach room temperature before use; shake before use.
- Store between +2°C to +8°C. Do not freeze. Store in original packaging. The vaccine should be protected from light at all times, (exposure may inactivate the virus).
- There is no evidence of risk from vaccinating those who are breast-feeding with inactivated virus vaccines (Please see relevant online Green book chapter, Tripartite Letter - PHE Gateway Ref:2017863 and the manufacturer's SPCs
- Have access to the current NYCC Influenza vaccines PGD, the latest SPC & BNF.
- If inadvertent administration of inappropriate flu vaccine type occurs then the advise in the ***"inactivated influenza vaccine guidance for healthcare practitioners***" by Public Health England must be followed; (https://www.gov.uk/government/publications/inactivated-influenza-vaccine-information-for-healthcare-practitioners?utm_source=16fffda5-).
- Equipment used for immunisation, including discharged vaccines in a syringe, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
- The pharmacist should have immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.
- Individuals should consent to information sharing with their GP practice as part of the consent process for accessing this service. Individuals who are not registered with a GP practice may be vaccinated at the professional discretion of the pharmacist, weighing up risks and benefits for the individual. They should be encouraged to register with a GP as appropriate to their circumstances or be referred to appropriate alternative medical services as required.

References

- **NHS Executive HSC 2000/026** (9th August 2000): Patient Group Directions [England only].
- **Department of Health (DH) & Public Health England (PHE) & NHS England Letter**: The national flu immunisation programme 2018/19 (26/03/2018): PHE Gateway Reference Number 2017863
- **Public Health England (PHE):** Vaccine Update, (August 2018).
- The national flu immunisation programme 2018 to 2019: supporting letter. Published 26 March 2018 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan
- Influenza vaccine ovalbumin content https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content
- Declaration of competence for vaccination services https://www.cppe.ac.uk/services/declaration-of-competence
- **PHE. Inactivated influenza vaccine information for healthcare practitioners** PHE publications gateway number: 2018250 https://www.gov.uk/government/publications/inactivated-influenza-vaccine-information-for-healthcare-practitioners Accessed 19/09/2018
- **Public Health England:** Immunisation Against Infectious Disease - The "Green Book" Chapter 19: Influenza (Aug 20158. Accessed at https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19 on 19/09/2018
- **Nursing and Midwifery Council (NMC), 2007**: Standards for Medicines Management.
- **Nursing and Midwifery Council (NMC), 2007**: Record Keeping Advice Sheet.
- **NMC, 2008**: Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- **Resuscitation Council (UK), October 2015**: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- Mylan Products Ltd, Influvac sub-unit® Tetra ▼ - **Summary of Product Characteristics (SPC)**, 02/08/18 (accessed from EMC on 16/08/2018).
- Mylan Products Ltd, Influenza vaccine Tetra MYL – **Summary of Product Characteristics**, 02/08/2018 (accessed from Electronic Medicines Compendium on 16/08/2018).
- Glaxo SmithKline UK, Fluarix® Tetra ▼ - **SPC**, 0729/017/20186 (accessed from EMC on 160/078/20187
- MASTA Ltd, Quadrivalent Influenza Vaccine (split virion, inactivated) ▼ , suspension for injection in prefilled syringe - **Summary of Product Characteristics** as per Sanofi Pasteur's Quadrivalent Influenza Vaccine (split virion, inactivated) ▼ .
- Sanofi Pasteur, Quadrivalent Influenza Vaccine (split virion, inactivated) ▼ , suspension for injection in prefilled syringe - **Summary of Product Characteristics**, 10/01/2018 (accessed from EMC on 16/08/2018).
- **Public Health England & Royal College of Nursing:** National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners (February, 2018). Accessed at https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners on 19/09/2018.

4. Characteristics of Healthcare Professional using this PGD

Only pharmacists that have been specifically authorised by their clinical lead or by self-declaration may use this PGD for the indications defined within it.

Qualification/registration requirements

Currently registered with the General Pharmaceutical Council (GPhC).

Additional requirements (applies to all staff)

- The pharmacist must be authorised by name as an approved practitioner under the current terms of this PGD before working under its authority (i.e. by completion of the Individual Healthcare Professional Authorisation).
- Must have undertaken appropriate training and maintain accreditation for working under PGDs for supply/administration of medicines as required by the community pharmacy seasonal influenza vaccination advanced service specification and the declaration of competence for vaccination services, as defined by the Centre for Pharmacy Postgraduate Education (CPPE) https://www.cppe.ac.uk/services/declaration-of-competence. Retention of all training documentation.
- Meet the National Minimum Standards and Core Curriculum for Immunisation Training as defined in the PHE & RCN publication, "National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners (February 2018)."
- Must be competent in the use of PGDs (see NICE competency framework for health professionals using patient group directions). https://www.nice.org.uk/guidance/mpg2/resources
- Maintain knowledge of vaccination products and alert to changes in their Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ("The Green Book"), and the national immunisation programme
- Must be competent to undertake immunisation and to discuss issues related to immunisation
- Must be competent in the handling and storage of vaccines, and management of the "cold chain" as outlined in the CPPE declaration of competence for vaccination services
- Must have up to date resuscitation skills, anaphylaxis training and be competent to recognise & manage anaphylaxis.
- Must have access to PharmOutcomes, current BNF, online Green Book and the PGD and associated online resources.
- By signing up to this PGD, the pharmacist accepts personal responsibility for working under its authority, understands the legal implications of doing so, and works within the scope of the PGD.
- It is the responsibility of the pharmacist to ensure that they have appropriate up to date knowledge of the medicine(s) prior to its supply/administration and to maintain this knowledge and keep up to date with relevant developments.
- The Provider will be required to comply with GPhC Standards of Conduct, Ethics and Performance and demonstrate maintenance of knowledge, skills and competencies, with evidence of Continuing Professional Development.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Any additional training requirements as deemed necessary by your organisation or the authorising body (in this incident the authorising body is North Yorkshire County Council).

Continued training requirements (applies to all staff)

- Pharmacists should ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD).
- Annual updates in immunisation (recommended).
- Pharmacists should be constantly alert to any subsequent recommendations from PHE and/or NHS England and other sources of medicines information. NB. The most current national recommendations should be followed. However, if updated recommendations mean that to vaccinate the individual would be outside the scope of this PGD, the individual should be referred to their GP for vaccination.
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Management & Monitoring of Patient Group Direction NYCC 2018/CP03

The Administration of Influenza (Seasonal Flu) Vaccines

INDIVIDUAL HEALTHCARE PROFESSIONAL AUTHORISATION

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named accredited pharmacist.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by the registered Healthcare Professional it applies to. Healthcare Professionals must be authorised before using the PGD. Pharmacists will be required to authorise themselves by having the relevant Declaration of Competence in place.
- By signing this document, the pharmacist confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD.
- Patient Group Directions should be used in conjunction with national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Agreement by Pharmacist

I _____ (name of healthcare professional), consider that I am competent to administer influenza vaccinations. I have completed all the necessary and appropriate training, which will allow me to provide this professional service while this PGD remains valid.

I have read and understood the Patient Group Direction

Influenza (Seasonal flu) Vaccines – Direction number: NYCC 2018/CP03

I agree to administer influenza vaccinations in accordance with this PGD (NYCC 2018/CP03). I will maintain clinical records as defined by the PGD, PharmOutcomes and in line with recognised governance standards.

Signature of Healthcare Professional: - _____

Date signed: _____ GPhC Registration no.:_____

Full premises address:……

……

Also complete next section if a manager/clinical lead is required to authorise you to use this PGD.

Authorisation from Manager/Clinical Lead to use this PGD:-

I confirm that the pharmacist named above has declared themselves suitably trained & competent to work under this PGD.

I give authorisation on behalf of …….. (INSERT NAME OF ORGANISATION) for the above named pharmacist who has signed the PGD to work under it.

Name of Manager/Clinical Lead: _____ Designation: _____

Signature of Manager/Clinical Lead: _____ Date signed: _____

PGD Valid from: 22nd October 2018	Review Date: - June 2020	**Expiry Date: - 30th Sept. 2020**