Patient Group Direction (PGD) for the Administration of

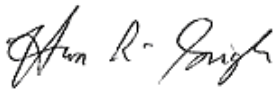
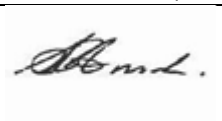
INFLUENZA (Seasonal Flu) VACCINE

by Community Pharmacists to Individuals Accessing NHS Services from Commissioned and Accredited Community Pharmacies in Durham, Darlington and Tees

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

Direction Number: - **NECSAT 2014/015**

Valid from:	1st September 2014
Review date:	1st July 2016
Expiry date:	**31st August, 2016**

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Medicines Optimisation Pharmacist (North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		22/08/2014
Medicines Optimisation Pharmacist (North of England Commissioning Support)	**Marie Thompkins** *(Senior Pharmacist)*		22/08/2014
Consultant Public Health Medicine (Public Health England, DDT)	**Dr Malathi Natarajan** *(Senior Doctor)*		28/08/2014
Immunisation and Screening Manager (Public Health England, DDT)	**Sandra Ansah** *(Senior Nurse)*		22/08/2014
Community Pharmacist (Chairman, Tees LPC)	**Jay Badenhorst** *(Community Pharmacist)*		29/08/2014

This PGD has been approved for use in Durham, Darlington and Tees by: -			
Title	Name	Signature	Date
Assistant Medical Director (DDT Team, NHS England)	**Dr James Gossow** *(Governance Authorisation)*		29/08/14

This PGD has been approved for use in Cumbria, Northumberland, Tyne & Wear by: -			
Title	Name	Signature	Date
Medical Director (CNTW Area Team, NHS England)	**Dr Mike Prentice** *(Governance Authorisation)*		01/09/14

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 (as per Public Health England Green Book Guidance)

[NB. Only use those criteria that are specific to your authorised role & competence. Ensure appropriate consent has been obtained before commencing any vaccination].

Eligible individuals are those falling into one or more of the following groups: *(For full details refer to Department of Health, Public Health England and NHS England tripartite letter 28/04/14. PHE Gateway ref.2013521,* Annex A to D.)

- **All those aged 65 years and over** (i.e. born before or on 31st March 1950)
- **All those aged 18 years old and older in the following risk groups: -**

a) ***Chronic respiratory disease****: i.e. asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission; Chronic obstructive pulmonary disease (COPD) including chronic bronchitis & emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD).*

b) ***Chronic heart disease*** *- This includes congenital heart disease and hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.*

c) ***Chronic kidney disease (CKD)*** *(CKD at stages 3, 4 or 5, chronic renal failure, nephrotic syndrome & renal transplantation)*

d) ***Chronic liver disease*** *(including cirrhosis, biliary artesia & chronic hepatitis).*

e) ***Chronic neurological disease*** *(stroke and transient ischaemic attack (TIA)).*

f) ***Diabetics*** *(Type 1 diabetics; Type 2 diabetics requiring insulin or oral hypoglycaemic drugs; diet controlled diabetics).*

g) ***Immunosuppression due to disease or treatment****. - Those treated or likely to be treated with systemic steroids for >1month at a dose equivalent to prednisolone at 20mg or more per day. HIV infection at all stages. Patients undergoing chemotherapy leading to immunosuppression. Bone marrow transplant patients; multiple myeloma or genetic disorders affecting the immune system;* ***(Please also refer to Precautions section)***

h) ***Asplenia or dysfunction of the spleen*** *– includes conditions such as homozygous sickle cell disease coeliac syndrome that may lead to splenic dysfunction.*

i) **Pregnant women** *–Women at any stage of pregnancy (first, second or third trimesters).*

- **Those living in long stay nursing or 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 offender's institutions or university halls of residence).
- **Those who are in receipt of a carer's allowance**, **or those who are the main carer** for an elderly or disabled person whose welfare may be at risk if carer falls ill. (NB. This category refers to individual carers entitled to a free flu vaccine on the NHS).

(See Public Health England "**Immunisation Against Infectious Diseases"** online chapter 19 – Influenza (July 2014) & PHE national flu immunisation programme 2014/15 Guidance for full details).

(Please refer to Community Pharmacy Service – Seasonal Influenza Immunisation Service level Agreement 2014/15 for additional information).

Exclusion criteria

General exclusions

- Under 18 years of age; No valid consent;
- Patients with a bleeding disorders diagnosis.
- Those who are taking an anticoagulant such as warfarin **whose INR >4.0**.
- Patient is acutely unwell (postpone vaccination until recovered. Minor illnesses without fever or systemic upset are not reasons to postpone immunisation).
- Confirmed anaphylactic reaction to a previous dose of any of the influenza vaccines.
- Confirmed anaphylactic reaction to any excipient, component or ingredient of any of the vaccines.
- Hypersensitivity to formaldehyde and eggs.

  NB. Egg allergic individuals can be immunised with an egg-free influenza vaccine if available (Optaflu® is currently the only available ovalbumin-free influenza vaccine)**. If no egg-free vaccine is available, patients should be referred to their medical practitioner.**

Specific exclusions (in addition to those listed above under general exclusions).

Hypersensitivities vary between products. Refer to individual SPC for full list of reactions and contraindications.

- For Agrippal - hypersensitivity to kanamycin, neomycin, cetyltrimethylammonium bromide, polysorbate 80 & barium sulphate.
- For *Enzira* - hypersensitivity to neomycin & polymyxin;
- For Fluarix Tetra - hypersensitivity to gentamicin sulphate & sodium deoxycholate
- For *Imuvac* - hypersensitivity to cetyltrimethylammonium bromide, polysorbate 80, or gentamicin.
- For Intanza 9mcg & 15mcg - hypersensitivity to neomycin & octoxinol 9
- For *Influvac sub-unit* - hypersensitivity to cetyltrimethylammonium bromide, polysorbate 80 or gentamicin.
- For *Inactivated Influenza Vaccine* (Split Viron) BP (Sanofi). - hypersensitivity to neomycin & octoxinol 9
- For *Inactivated Influenza Vaccine* (Split Viron) BP (MASTA). - hypersensitivity to neomycin & octoxinol 9
- For CSL *Inactivated Influenza Vaccine* (Split Viron) Ph.Eur. (Pfizer) - hypersensitivity to neomycin & polymixin.
- For Optaflu (Novartis) - Hypersensitivity to any excipient.

Please refer to Green Book Chapter 19 - Influenza (July 2014) on-line version, current SPC and BNF for full details.

Precautions

- It is difficult to define what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered influenza vaccination. This decision is best made on an individual basis and left to patient's clinician. Some immunocompromised patients may have a suboptimal immunological response to the vaccine.
- Hypersensitivity reactions to previous dose of vaccine or component of the vaccine:

  NB. "Local adverse reactions that generally start within a few hours of the injection and 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."

Action if excluded

- Advise individual to attend their GP practice for vaccination.
- Complete any relevant records/referral paperwork as required by the Service Level Agreement (SLA) as applicable.
- If the individual has a bleeding disorder, refer to GP for subcutaneous injection.
- If postponement due to acute illness, arrange a future date for immunisation

Action if patient declines treatment

- Ensure patient, fully understands the risk of influenza infection and the risks and benefits of the vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications.
- Document refusal, advice given, actions/decisions in notes (written or electronic).
- Inform or refer to doctor as appropriate. Complete any relevant paperwork as appropriate
- Signpost to primary care for more information/vaccination

3. Description of Treatment.

Name, strength & formulation of drug:

Inactivated Influenza Vaccine 0.5ml Pre-filled Syringe (PFS);
NB. This PGD is only for individuals aged 18 years old and over.
The tabulated information is taken from the manufacturer's SPC and the Green Book on-line Influenza chapter 19.
Brand(s) as recommended and supplied for 2014/2015 Influenza Immunisation Programme are: -

Supplier	Name of product	Vaccine Type	Ovalbumin content (µg/ dose)	Age Indication
Abbott Healthcare	**Influvac sub-unit ®**	Surface antigen, Inactivated, sub-unit	0.1mcg / 0.5ml dose	All these vaccines are suitable for 18 years old and over.
	Imuvac®		0.1mcg / 0.5ml dose	
GlaxoSmithKline	**Fluarix ® Tetra ▼**	Inactivated virus	≤ 0.05mcg / 0.5ml dose	
MASTA	**Imuvac®**	Inactivated, sub-unit	0.1mcg / 0.5ml dose	
	Inactivated influenza vaccine (Split Virion) BP	Inactivated, split virion,	≤ 0.05mcg / 0.5ml dose	
	Enzira ®	Inactivated virus	≤ 1.0mcg / 0.5ml dose	
Novartis Vaccines	**Agrippal®**	Surface antigen, inactivated virus.	≤ 0.2mcg / 0.5ml dose	
	Optaflu® ▼		**No ovalbumin**	
Pfizer Vaccines	**CSL Inactivated Influenza vaccine** (Split Virion) **Ph.Eur**	Inactivated, split virion,	≤ 1.0mcg / 0.5ml dose	
	Enzira®		≤ 1.0mcg / 0.5ml dose	
Sanofi Pasteur MSD	**Inactivated influenza vaccine BP**	Inactivated, split virion,	≤ 0.05mcg / 0.5ml dose	
	Intanza® 9mcg	Inactivated split virion, intradermal	≤ 0.024mcg / 0.1ml dose	**From 18 to 59 years**
	Intanza® 15mcg		≤ 0.024mcg / 0.1ml dose	**From 60 years**

▼ Black Triangle Drug (under intensive surveillance).

None of the influenza vaccines for 2014/15 season contain thiomersal as an added preservative. Other than localised sensitivity, levels of thiomersal in vaccines are not associated with any harm, including in children, pregnant women and their offspring.

Legal Status:

POM – Prescription Only Medicines

Dosage/Dose range:

Age of individual	Dose	Name of product
18 years of age and over	Single (IM) injection of 0.5ml	Inactivated intramuscular vaccine **Brands include:** Agrippal® , Enzira® , Fluarix®▼ Tetra , Imuvac®, Influvac sub-unit®, CSL Inactivated Influenza Vaccine (Split Virion) BP (by Pfizer Vaccines) Inactivated Influenza Vaccine (Split Virion) BP (by MASTA) Inactivated influenza vaccine (Split Virion) BP (by Sanofi Pasteur MSD), Intanza® 9mcg, Intanza® 15mcg, Optaflu® ▼
Adults aged 18 years to 59 years old	Single injection of **0.1ml**	Inactivated intradermal vaccine **Intanza® 9mcg**
Adults aged 60 years and older	Single injection of **0.1ml**	Inactivated intradermal vaccine **Intanza® 15mcg**

Route/Method:

- **Inactivated influenza vaccines** given by **Intramuscular (IM) Injection**
  This should be given preferably into the upper arm (deltoid region)
- **INTANZA®** vaccine is an intradermal injection. (Please refer to SPC or Green book for administration advice).
  Other vaccines can be given at the same time as influenza vaccine. Vaccines should be given at separate sites, preferably in a different limb. If given in the same limb, they should be given at least 2.5cm apart.

Frequency of Administration: -

Annual (One in each influenza season)

Maximum dose:

0.5ml (for Inactivated Influenza Vaccine brand listed above)
0.1ml (for Intanza 9mcg and Intanza 15mcg)

Maximum number of vaccinations:

One dose

Follow up treatment: -

Annual revaccination / as above

4. 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 & Intradermal Inactivated Influenza Vaccines (various brands)
Very Common & Common Reactions	Injection site pain, swelling and redness, ecchymosis and induration*. Low grade fever, shivering, fatigue, headache*, myalgia, arthralgia* and sweating*. Malaise within 48hours post vaccination. *These reactions usually disappear within 1-2 days without treatment.
Uncommon Effects	See Individual SPC's
Rarely	Anaphylaxis, neuralgia, convulsions, transient thrombocytopenia, paraesthesia, and vasculitis.

See manufacturers Summary of Product Characteristics for details of all potential adverse reactions & their 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.
- Please refer to www.mhra.gov.uk/yellowcard and Green Book- Chapter 9 (20th March 2013).

Identification and Management of Adverse Reactions

- See anaphylaxis guidelines. Patient/Parent/Guardian requested to report side effects
- **Advice on management**: - Chapter Eight of the Green Book provides detailed advice on managing ADRs following immunisation, e.g. Analgesia for pain/fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor or other service as appropriate

Advice to Patient/Carer (verbal or written)

- Provide a patient information leaflet and discuss as required.
- Explain vaccination procedure and protection level expected from vaccine.
- Provide advice on & explain potential warnings & side effects/adverse reactions.
- Advise on treatment for post immunisation pyrexia, pain etc.
- Provide advice on management of adverse reactions (see above).
- Explain procedure for dealing with anaphylaxis /severe allergic reactions.
- Explain the "Out of Hours" procedure.
- Provide patient with post vaccination information/record card if applicable, within the service level agreement.

Arrangements for Referral to Medical Advice

- Advise individual to speak to their pharmacist / GP where necessary
- Advise individual to access local out of hours NHS services, e.g. NHS 111 as appropriate.

Records

The following must be recorded in the patient's notes: -

- Patient's name and date of birth; Reason vaccination required; Dose, site and route of injection;
- Date of administration; Brand name, batch number and expiry date of vaccine;
- Whom administered by and signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed;
- Support literature given (where applicable). Any further details as required by the Service Level Agreement

Additional Facilities

- Access to a current BNF. All staff are familiar with and have online access to the latest edition of the Green Book, noting the clinical guidance may change and that the Green Book is frequently updated.
- A consultation area approved for this service.
- Cold chain facilities (store vaccines in a refrigerator (+2º C to + 8º C). Discard if frozen).
- Hand washing facilities/equipment is readily available.
- Stock control & storage/disposal of vaccines in accordance with standard practice / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline).
- Any additional requirements as details in the SLA

Special Considerations / Additional Information

- **Vaccines should be allowed to reach room temperature before use**; shake and visually inspect before use.
- Please consult individual SPC's for additional information

References

- **NHS England**, Area Team (DDT) –Community Pharmacy Service – Seasonal Influenza Immunisation SLA 2014/15,
- ***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 flu immunisation programme 2014/15 (28/04/14): PHE Gateway Reference 2013521.
- ***Public Health England:*** Immunisation Against Infectious Disease - The "Green Book" Chapter 19: Influenza (July 2014). Accessed at https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19 on 12/08/14.
- ***Royal Pharmaceutical Society (July 2014)***: Medicines, Ethics and Practice. Edition 38 (July 2014).
- ***Resuscitation Council (UK), October 2010***: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- Abbott H/C Products Ltd, Influvac sub-unit ® - ***Summary of Product Characteristics***, 04/08/14 (accessed from EMC on 12/08/14).
- Abbott Healthcare Products Ltd, Imuvac ® - ***Summary of Product Characteristics***, 04/08/14 (accessed from EMC on 12/08/14).
- Glaxo SmithKline UK, Fluarix® Tetra ▼ - ***Summary of Product Characteristics***, 24/06/14 (accessed from EMC on 12/08/14).
- Novartis Vaccines, Agrippal® - ***Summary of Product Characteristics***, 25/07/14 (accessed from EMC on 12/08/14).
- Novartis Vaccines, Optaflu® - ***Summary of Product Characteristics***, 07/11/13 (accessed from EMC on 12/08/14).
- Pfizer Limited, Influenza vaccine (split virion, inactivated), pre-filled syringe® - ***Summary of Product Characteristics***, 26/07/13 (accessed from Electronic Medicines Compendium on 25/07/14).
- Pfizer Limited, Enzira® - ***Summary of Product Characteristics***, 25/07/14 (accessed from EMC on 12/08/14).
- Sanofi Pasteur MSD Ltd., Inactivated influenza vaccine (split virion) BP, suspension for injection in prefilled syringe - ***Summary of Product Characteristics***, 26/07/13 (accessed from EMC on 12/08/14).
- Sanofi Pasteur MSD Ltd., Influenza vaccine (split virion inactivated), - ***Summary of Product Characteristics*** (SPC), 29/08/13 (accessed from Electronic Medicines Compendium on 12/08/14).

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists
State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.		

Qualifications required (professional registration applies to specific professions**)**

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council (HPC)

Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the HPA National minimum standards in immunisation training 2005 either through training or professional competence.
- Meeting all training/competence requirements as defined in the service level agreement for this programme.
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and current *Immunisation against infectious disease* (Green Book).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

Continued training requirements (applies to all staff)

- Annual attendance at an update on resuscitation skills and the management of anaphylaxis within the community/primary care **(mandatory).**
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation **(recommended).**
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Management & Monitoring of Patient Group Direction NECSAT 2014/015

The Administration of

INFLUENZA VACCINE (Seasonal Flu Vaccine)

This form is to be used for the purpose of managing, monitoring and authorising the use of this PGD by the named accredited pharmacist.

- This PGD is to be read, agreed to and signed by all registered healthcare professionals it applies to.
- By signing this document, the healthcare professional 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).
- One signed copy should be given to each healthcare professional with the original signed copy being kept on file by the Manager/Clinical Lead with responsibility for maintaining PGDs.
- Patient Group Directions should be used in conjunction with reference to 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.

Name of Healthcare Professional:-_____

is authorised to administer

INFLUENZA VACCINE (Seasonal Flu Vaccine)

……under this Patient Group Direction (NECSAT 2014/015)

(By signing this document the pharmacist is stating that they are competent to work under this PGD & accept full clinical responsibility for any decisions made through the use of this PGD).

Signature of accredited Pharmacist: - _____

Date signed: - _____

State GPhC number: - _____

<u>This above named healthcare professional has been authorised to use this PGD by: -</u>

* (Important note: Where a pharmacist does not have a manager or clinical lead available to authorise them, then the community pharmacist will be required to authorise themselves)

***Name of Manager/Clinical Lead: - _____

Signature of authorising Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from:1st Sept. 2014	Review Date: - July 2016	**Expiry Date: - 31st August 2016**