NHS Commissioning Board

Service Level Agreement for Seasonal Flu Immunisation Programme under a Patient Group Direction (PGD)

Contents:

1. Financial Details

1.1 This agreement is to cover 7 months commencing 1 September 2013 and will terminate on 31 March 2014.

On agreeing the service plan with the NHS Commissioning Board for the 7 months commencing 1 September 2013, pharmacies will receive monthly remuneration retrospectively to each pharmacy according to the following tariff:-

1.2 Invoices for activity will automatically be generated by Pharmoutcomes at the end of each month and processed by the commissioner or its agent. Payment will be due at the end of the month.

The principal purpose of flu immunisation, which is carried out by a trained pharmacist, is to protect or maintain the health of the individual receiving the immunisation. The vaccine is personally administered and integral to the provision of that service. As such this is an exempt activity under schedule 9 of the VAT act 1994, and there is no requirement to account for any VAT element in the professional fee.

PAYMENT FOR EACH IMMUNISATION WILL ONLY BE MADE UPON RECEIPT OF THE COMPLETED SIGNATURE SHEET

2. Signature Sheet

2.1 This document constitutes the agreement between the pharmacy and the NHS Commissioning Board with regard to the **Service Level Agreement for Seasonal Flu Immunisation Programme under a Patient Group Direction.**

2.2 By signing up to this Service Level Agreement, you are agreeing that you fully comply with the Terms of Service as outlined in the NHS Pharmaceutical Services Regulations 2013 and agree to comply with the full terms and conditions as outlined in this Service Level Agreement.

2.3 Failure to comply with the full terms and conditions as outlined in this Service Level Agreement may result in suspension of the scheme. Before any suspension the provider and commissioner will discuss the reason for the suspension to identify a possible resolution.

NAME AND ADDRESS OF PHARMACY:

……

……

Names of Pharmacists undertaking the service

……

……

……

Signature on behalf of the Pharmacist:

Signature	Name	Date

Signature on behalf of the Commissioning Board:

Signature	Name	Date
	Dr Claire Bradford	1/10/2013

Please return completed SLA to Linda Bosher linda.bosher@nhs.net

3. Service Description

3.1 The overarching national service specification is Service Specification No. 13, Seasonal Flu Immunisation Programme published by NHS England (SS13). This document adds operational detail for the Community Pharmacy Seasonal Flu Immunisation Service.

3.2 This service will require the pharmacist to administer flu immunisation to eligible adult patients as detailed in the NHS England approved Client Group Direction.

4. Aims and Intended Service Outcomes

4.1 The purpose of the service level agreement (SLA) is to cover the provision of seasonal flu immunisation for people identified as being in the 65+ age group, or in the at-risk adult groups as defined by the Department of Health for the 2013/14 flu season.

4.2 The intended service outcome is to reduce the serious morbidity and mortality from flu infections by immunising those most likely to have a serious or complicated illness should they develop flu infection. This can avert the need for hospitalisation.

4.3 The purpose of the SLA for the Seasonal Flu Immunisation Programme 2013/14 is to commission local community pharmacy to provide a flu immunisation service in addition to that provided by GP practices.

5. Service Outline

5.1 It is the responsibility of each pharmacy to identify adult patients who are in the at-risk groups specified in the Patient Group Direction (PGD) inclusion criteria. Patients aged 65 or over would need to provide proof of age. Patients who are under 65 are required to provide proof of eligibility for example a personalised GP invitation letter or their Patient Medication Record (PMR). Pregnant women may not have had a letter; in which case self-identification is acceptable (most will have pregnancy notes, or a doctors letter or a MATB1).

5.2 If there is doubt about eligibility, the client should be asked to return with the letter before vaccine is administered, or eligibility can be confirmed with their GP practice.

5.3 Children up to and including the age of 17 are EXCLUDED from this service, regardless of any risk group that they fall into. If a child or their parent/s/guardians presents requesting a flu immunisation, the pharmacist must refer them to their GP practice.

5.4 2013/14 Eligibility

- people aged 65 years or over (including those becoming age 65 years by 31 March 2014)
- all pregnant women (including those women who become pregnant during the flu season)
- people with a serious medical condition such as: chronic (long-term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis
- chronic heart disease, such as heart failure
- chronic kidney disease at stage 3, 4 or 5
- chronic liver disease
- chronic neurological disease, such as Parkinson's disease or motor neurone disease
- diabetes
- a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)
- people 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, for instance, prisons, young offender institutions, or university halls of residence
- people who are in receipt of a carer's allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill

Please note that frontline health and social care staff are not eligible for free immunisation under this SLA, but nevertheless could be vaccinated either at their own or their employer's expense.

5.5 The client may present the invitation letter sent by or on behalf of their GP practice. Patients with a PMR at the pharmacy may be confirmed as eligible without the letter.

5.6 Patients meeting the inclusion criteria will be offered the opportunity of receiving a flu immunisation free of charge at the pharmacy, administered by an accredited pharmacist under the authority of a PGD.

5.7 Inclusion and exclusion criteria, detailed in the PGD, will be applied during the provision of the service. Where clinical contraindications, as stated in the PGD, preclude the administration of the immunisation, the client should be referred to their GP for further advice.

5.8 Any revision in the at-risk groups as defined by the Department of Health will be notified to participating pharmacies.

5.9 Pharmacies may begin immunisation from 1st September 2013, and will be required to advertise and promote the service for the period up to 31st March 2014.

5.10 Vaccine purchase is the responsibility of the pharmacy. The cost of the vaccine is inclusive in the £12.00 remuneration fee as per 1.1 of this SLA.

5.11 The pharmacy contractor must have a standard operating procedure in place for this service, which should include procedures for maintaining cold chain integrity (storage of vaccines in line with manufacturer's instructions, recording of max/min temperatures, stock rotation checks).

5.12 The pharmacy contractor should ensure that staff are made aware of the risk associated with handling clinical waste. A needle stick injury procedure should be in place. Participating pharmacists are strongly encouraged to maintain current immunisation against Hepatitis B infection.

5.13 Patients must be registered with a General Practice in the Cumbria, Northumberland, Tyne & Wear Area Team area. They can be made aware of the service by the pharmacy, other pharmacies, their General Practice, or self refer.

- Pharmacists can immunise the client, offer advice or refer them to their GP practice.

- The pharmacist will confirm with the client that they are eligible for immunisation, i.e. in one of the 'at-risk' groups defined by the Department of Health. Prior to administration the client should be supplied with a copy of the vaccine client information leaflet. This can be accessed from the seasonal flu immunisation service section in PHARMOUTCOMES, the web-based recording platform for pharmacy enhanced services

- The Flu Consultation Form(FCF) or equivalent will be used to record all details of the consultation, including client consent, and a copy of this will be used to notify the client's GP surgery that immunisation has taken place. This form must be retained for 7 years in the pharmacy. A claim for the immunisation will be made in the relevant 'services' section of Pharmoutcomes, using the information recorded on the FCF. A separate note should also be made on the PMR system, noting the date of immunisation, or other outcome if immunisation was not completed.

- The client's GP should be informed that immunisation has taken place as soon as possible, either immediately by fax or in a manner agreed locally, which must always provide a daily update of immunisations to each GP surgery (on weekdays)

- NHS England will be updated with immunisation activity by access to Pharmoutcomes.

5.14 The FCF must be completed fully before being sent to the relevant GP practice. This document includes:

a) Client identifier
b) Consent signature
c) The batch no., expiry date, name of the vaccine & manufacturer
d) Site of administration – for example, left or right deltoid muscle
e) The date of administration
f) Any contraindications to immunisation
g) Any adverse reactions to immunisation

5.15 Pharmacists should report any suspected adverse reaction to the Medicines & Healthcare Regulatory Agency (MHRA) using the Yellow Card reporting scheme (www.yellowcard.gov.uk)

6. Pharmacy and Pharmacist Eligibility / Criteria and Accreditation

6.1 Qualifications/Experience

6.1.1 The pharmacy contractor is responsible for ensuring the requirements for staff training are in place and staff involved in the administration of the vaccine must:

a) Have attended a formal immunisation training programme and have the necessary skills & competencies together with documented evidence of that training. This is to include vaccine administration, anaphylaxis recognition & treatment, basic life support, cold chain integrity & infection control.

b) If previously trained as specified in 6.1.1 (a), they must subsequently complete an annual update in the recognition and treatment of anaphylaxis together with basic life support.

c) Pharmacists administering less than 30 vaccines in any preceding year must repeat full training as specified in 6.1.1 (a).

d) Have completed training to work under PGDs.

6.1.2 Pharmacists responsible for immunisation must be signed up to work under the current seasonal flu PGD. A signed copy must be kept in the pharmacy.

6.1.3 Pharmacists providing this service are advised to ensure they are up to date with Hepatitis B immunisation (see 5.12)

6.1.4 It is the responsibility of participating pharmacists to ensure that their professional indemnity insurance covers them to provide immunisation services.

6.1.5 The pharmacy contractor must nominate a named person(s) within the community pharmacy who will be responsible for the administration of the flu campaign and advise the NHS England AT of their name(s).

6.2 Equipment/Premises

6.2.1 The pharmacy contractor is responsible for ensuring the requirements for equipment and premises are in place and must ensure that resuscitation equipment is accessible at all times during an immunisation session.

The resuscitation pack must contain the following:

Preferred option: 3 ampoules of adrenaline 1 in 1000 (1mg/ml) 500mcg to be administered sub-cutaneously or intra-muscularly every 5 minutes as specified in the immunisation Green Book and Resuscitation Council Guidelines.

OR an adrenaline 300mcg auto injector (Jext®, Epipen® - note that Jext® has a longer shelf life) for use in adults & children over 30kg. administering up to 3 over 15 minutes IF ADRENALINE AMPOULES ARE UNAVAILABLE

A selection of 1ml syringes and green needles – only if adrenaline ampoules are kept.

A pocket mask with one way valve

Disposable gloves

6.2.2 The pharmacy contractor is responsible for ensuring a suitable area for consultation with the client is in place. This suitable area:

- must be a quiet area within the premises which is separated from the area accessible by the general public
- must be clear and uncluttered
- must have an impermeable flooring
- must have a chair for patients to sit on during vaccine administration; the chair must be covered in impermeable material which will withstand a chlorine releasing agent for disinfection purposes
- must have facilities for patients to be able to lie down in the event of a simple faint or anaphylactic reaction
- must have access to dedicated hand washing facilities with liquid soap, disposable paper towels in a wall mounted dispenser and foot operated pedal bin
- must have disposable vomit bowls available in the immunisation area
- must have a sharps bin and sharps collection and disposal procedure in place

7. Quality Indicators

7.1 The pharmacy must review its standard operating procedures and the referral pathways for the service on an annual basis.

7.2 The pharmacy must participate in any audit of service required by NHS England.

7.3 The pharmacy must co-operate with any assessment of service user experience specified by NHS England.

Patient Group Direction (PGD) for the Administration of

INFLUENZA (Seasonal Flu) VACCINE

by Registered Professionals to Individuals Accessing NHS Services in Cumbria, Northumberland , Tyne & Wear

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

Direction Number: - **NECSAT 2013/005**

Valid from:	9th September 2013
Review date:	1st June 2015
Expiry date:	**8th September 2015**

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)*	Hira R. Singh	5/9/13
Consultant Public Health Medicine (Public Health England, Durham, Darlington & Tees)	**Dr Malathi Natarajan** *(Senior Doctor)*	M. Natarajan	5/9/2013
Immunisation and Screening Manager (Public Health England, Durham, Darlington & Tees)	**Nicola Clark** *(Senior Nurse)*	N Clark	5/09/2013

This PGD has been approved for use in Cumbria, Northumberland, Tyne & Wear: -

Title	Name	Signature	Date
Medical Director (Cumbria, Northumberland, Tyne& Wear)	**Dr Mike Prentice** *(Governance Authorisation)*	M Prentice	19/9/13

1. 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 ensuring that annual training is offered to all staff
- 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 *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 accredited 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.

2. 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 please refer to the Department of Health, Public Health England and NHS England tripartite letter 05/06/13. Gateway ref: 00157.* Annex A to D.)

- **All those aged 65 years and over** (i.e. born before or on 31st March 1949)
- **Children aged 2 and 3 years** (but not 4 years old or older) on 01/09/13
- **All those aged 6 months or 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). In addition, children who have previously been admitted to hospital for lower respiratory tract disease.*

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). Conditions in which respiratory function may be compromised (e.g. polio syndrome sufferers).*

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

g) ***Immunosuppression due to disease or treatment****. Asplenia or splenic dysfunction; those treated or likely to be treated with systemic steroids for >1month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kgs a dose of 1mg or more per kg per day (any age).* ***HIV infection*** *at all stages.* ***Patients undergoing chemotherapy leading to immunosuppression.*** *Household contacts of immunocomprimised individuals may be considered, i.e. those who expect to share living accommodation on most days over the winter. This may include carers (see below).*

h) **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, not professional health & social care workers who should be vaccinated by their employer as part of an occupational health programme.
- **Any individual patient** whom the GP considers that the risk of influenza infection exacerbating any underlying disease that the patient may have, as well as the risk of serious illness from influenza itself warrants vaccination, e.g. patients with multiple sclerosis, cerebral palsy & related conditions; degenerative diseases of the CNS or muscles; or severe neurological disability. Influenza vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above.
- **Professional Health & social care workers who are in direct contact with patients/clients.** NB. Employers are responsible for ensuring that arrangements are in place for vaccination as part of an occupational health programme.
- **Others involved indirectly in delivering health care** such that they and vulnerable patients are at increased risk of exposure to seasonal flu.

(See PHE Guidance "**Immunisation Against Infectious Diseases**" updated chapter 19 (August 2012) & PHE Guidance for full details).

Exclusion criteria

General exclusions

- No valid consent;
- Under 6 months of age;
- Have a febrile illness or an acute infection/severe systemic illness. In this case vaccination should be postponed until patient recovered, (Minor infections without fever/systemic upset are not reasons to postpone immunisation).
- Confirmed anaphylactic reaction to a previous dose of any influenza vaccine.
- Confirmed anaphylactic reaction to any component, ingredient, or excipient of any of the influenza vaccines.
- Hypersensitivity to formaldehyde, chicken protein & eggs.

  NB. Egg allergic individuals must use influenza vaccines with an ovalbumin content of < 0.12mcg/ml (i.e. containing less than 0.06mcg per 0.5ml dose) (2012 guidance).

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.
- For *Enzira* - **children aged under 5 years.**
  - hypersensitivity to neomycin & polymyxin;
- For *Fluarix* - hypersensitivity to gentamicin sulphate & sodium deoxycholate
- For Fluarix Tetra - **children less than 3 years old**;
- - hypersensitivity to gentamicin sulph. & sodium deoxycholate
- For *Fluvirin* - **children under 4 years;**
- - hypersensitivity to betapropriolactone, nonoxynol 9, neomycin and polymixin;
- For *Imuvac* - hypersensitivity to cetyltrimethylammonium bromide, polysorbate 80, or gentamicin.
- For *Influvac Desu* - hypersensitivity to cetyltrimethylammonium bromide, polysorbate 80 or gentamicin.
- For Inflexal V * - hypersensitivity to neomycin and polymyxin B.
- For *Inactivated Influenza Vaccine* (Split Viron) BP (Sanofi). - hypersensitivity to neomycin & octoxinol 9
- For CSL *Inactivated Influenza Vaccine* (Split Viron) Ph.Eur. (Pfizer) - hypersensitivity to neomycin & polymixin.
  - children aged under 5 years
- For Intanza (15mcg/strain) - Individuals under 60 years old;
  - hypersensitivity to neomycin and octoxinol 9.
- For Intanza (9mcg/strain) - **adults 60 years old and over;** hypersensitivity to neomycin and octoxinol 9;
  - children and adolescents under 18 years old.
- For Optaflu (Novartis) - **individuals under 18 years old.**
  - hypersensitivity to any excipient.
- For Viroflu * - hypersensitivity to neomycin and polymyxin B.

* Viroflu and Inflexal V may be associated with a higher than expected rate of fever in children under five years. (See also "Relevant Warnings" section of this PGD). **Please refer to Green Book Chapter 19 - Influenza (August 2012) for full details.**

Please also refer to current SPC for each vaccine and the current BNF for full list of details.

Exclusion criteria - continued

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

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

For Fluenz ®

- individuals under 2 years of age.
- adults 18 years old and over;
- children aged 4 to 17 years old who are **not in a clinical risk group category** listed in Chapter 19 of the Immunisation Against Infectious Disease: The Green Book.
- hypersensitivity to gelatine, gentamicin & excipients;
- individuals with confirmed anaphylaxis to egg. NB. There are no data on use of Fluenz® in children with egg allergy;
- pregnancy & breast feeding. Clinically severely immunodeficient due to conditions or immunosuppressive therapy such as: acute and chronic leukaemias; lymphoma;
- those receiving salicylate therapy and children with active wheezing at the time of vaccination or severe asthma (BTS SIGN step 4 or above). Not to be given concomitantly with antiviral agents;
- HIV infection not on highly active antiretroviral therapy (HAART). Cellular immune deficiencies;
- high dose corticosteroids (at least 2mg/kg/day for a week or 1mg/kg/day for a month);

  (NB. It is not contraindicated for use in children or adolescents with HIV infection receiving stable antiretroviral therapy; or who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or those receiving corticosteroids as replacement therapy, e.g. for adrenal insufficiency (refer to Green Book, Chapter 19 & SPC)).
- **Temporary Exclusion**

  Administration of Fluenz® should be postponed in infants and children suffering from heavy nasal congestion. This is because heavy congestion may impede delivery of the vaccine to the nasopharyngeal mucosa.

*** Please refer to Green Book Chapter 19 - Influenza (August 2012) for full details.**

Action if excluded

- Discuss with or refer to clinician/doctor. Ensure all actions/decisions are documented.
- If postponement due to acute illness, arrange a future date for immunisation
- Individuals with confirmed anaphylaxis to egg can be immunised with an egg-free influenza vaccine if available, or referred to specialists for vaccination in hospital using an inactivated influenza vaccine with ovalbumin content less than 0.12µg/ml.

Action if patient declines treatment

- Ensure patient/parent/guardian fully understands the risks of declining vaccination & action to take if exposed.
- 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.

3. Description of Treatment.

Name, strength & formulation of drug:

Inactivated Influenza Vaccine 0.5ml & 0.25ml Pre-filled Syringe (PFS);
Attenuated Live Influenza Vaccine as a 0.2ml / dose Nasal Spray.
Brand(s) as recommended and supplied for 2013/2014 DH Influenza Immunisation Programme are: -

Supplier	Name of product	Vaccine Type	Age indications	Ovalbumin content (µg/ dose)
Abbott Healthcare	**Influvac Desu®**	Surface antigen, Inactivated, sub-unit	**From 6 months**	0.1mcg / 0.5ml dose
	Imuvac®			
AstraZeneca UK Ltd	**FLUENZ® ▼**	Live, attenuated (Nasal spray susp.)	**From 24 months** to less than 18yrs of age	≤ 0.24mcg / 0.2ml dose
GlaxoSmithKline	**Fluarix®**	Inactivated virus	**From 6 months**	≤ 0.05mcg / 0.5ml dose
	Fluarix ® Tetra ▼		**From 3 years**	
Janssen-Cilag Ltd (formerly Crucell UK)	**Viroflu® ***	Surface antigen, inactivated virosome	**From 6 mths** (but see adverse drug reaction on use in those aged 6 mths to under 5yrs)	≤ 0.05mcg / 0.5ml dose
	Inflexal®V *			
MASTA	**Imuvac®**	Inactivated, sub-unit	**From 6 months**	0.1mcg / 0.5ml dose
	Inactivated influenza vaccine (Split Virion) BP	Inactivated, split virion,	**From 6 months**	≤ 0.05mcg / 0.5ml dose
	Fluarix®	Inactivated virus	**From 6 months**	≤ 0.05mcg / 0.5ml dose
Novartis Vaccines	**Agrippal®**	Surface antigen, inactivated.	**From 6 months**	≤ 0.2mcg / 0.5ml dose
	Fluvirin® **		**From 4 years**	≤ 1.0mcg / 0.5ml dose
	Optaflu® ▼		**From 18 years**	No ovalbumin
Pfizer Vaccines	**CSL Inactivated Influenza † vaccine** (Split Virion) **Ph.Eur**	Inactivated, split virion,	**From 5 years**	≤ 1.0mcg / 0.5ml dose
	Enzira® †			
Sanofi Pasteur MSD	**Inactivated influenza vaccine BP**	Inactivated, split virion,	**From 6 months**	≤ 0.05mcg / 0.5ml dose
	Intanza® 9mcg	Inactivated split virion, intradermal	**From 18 to 59 years**	≤ 0.024mcg / 0.1ml dose
	Intanza® 15mcg		**From 60 years**	

▼ Black Triangle Drug (under intensive surveillance).

None of the influenza vaccines for 2013/14 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.

** Fluvirin vaccine contains traces of thiomersal that are left over from the manufacturing process.

* Viroflu and Inflexal V may be associated with a higher than expected rate of fever in children under five years. (See also "Relevant Warnings" section of this PGD).

† There are an increased number of reports of fever in the age group 5 to less than 9 years with these vaccines. (Please refer to relevant SPCs & Green Book Chapter 19 - Influenza).

Legal Status: **POM** – Prescription Only Medicines

Dosage/Dose range:

Children 6 months to less than 9yrs old in clinical risk groups:
Those not previously vaccinated, a second dose should be given after an interval of at least 4 weeks (depending on the manufacturers SPC).
For Fluenz this applies to children from 2 years to less than 9 years old. An interval of 4 weeks between the 1st dose and 2nd dose should also be used (as per JCVI recommendations).

Fluenz® is the vaccine of choice for children in clinical risk groups aged 2-17 years as it has been shown to provide a higher level of protection for children than inactivated influenza vaccine.

DH recommends 0.5ml now given to children 6mths & older where there is a choice of either 0.25ml or 0.5ml
Please also refer to Section 3 for specific age and doses.

Age of individual	Dose	Vaccine type this applies to
6 months and older and adults (Some of the vaccines are not authorised for young children – see Section 3)	Single injection of **0.5ml** Children aged 6 months to less than 9years who have not received influenza vaccine before should receive a 2nd dose of vaccine at least 4 weeks later.	Inactivated intramuscular vaccine **Brands include:** Agrippal® , Enzira® , Fluarix® , Fluvirin®, Imuvac®, Inflexal®V, Influvac Desu®, Inactivated influenza vaccine (Split Virion) BP (by Sanofi Pasteur MSD), Influenza vaccine (split virion, inactivated) by Sanofi Pasteur MSD, Viroflu®
Children aged 2 to 17 years old • Infants aged 2 and 3 years. • Children aged 2 to 17 years in a clinical at risk group category (listed in chapter 19 of the Immunisation Against Infectious Disease: The Green Book)	Application of one **0.2ml** dose (administered as 0.1ml in each nostril) * NB. For those who have not received an influenza vaccine before, a 2nd dose should only be offered to children aged 2 to less than 9 years in a clinical at risk group. The interval between doses should be at least 4 weeks.	Live attenuated intranasal vaccine **Fluenz® ▼** nasal spray suspension (Fluenz® is the vaccine of choice for children in clinical risk groups aged 2-17 years old) (see contraindications for use)
3 years old and over	Single injection of **0.5ml**	**Fluarix® Tetra ▼**
4 years old and over	Single injection of **0.5ml**	**Fluvirin®**
5 years old and over	Single injection of **0.5ml**	**Enzira® / CSL (Pfizer) Influenza vaccine (split virion, inactivated), pre-filled syringe**
18 years old and over	Single injection of **0.5ml**	**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**

* See Tripartite letter "The Flu immunisation programme 2013/14-extension to children," JCVI advice, page 6 (Gateway reference 00275). The SPC states that 2 doses should be offered to any child aged 2 to less than 9 years who has not received flu vaccine before. However, JCVI guidance states that 1 dose is sufficient and only 2 doses should be offered if the child in this age range is in a clinical at risk group.

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).
- **INTANZA®** vaccine is an intradermal injection. (Please refer to SPC or Green book for administration advice).
- **Fluenz®** (live attenuated vaccine) is administered by the intranasal route. An applicator is supplied that allows a divided dose of to be administered in both nostrils (total dose of 0.2ml, 0.1ml in each nostril).

  Where protection for influenza is needed vaccination should not be delayed due to the administration of another live vaccine.
- 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 (see also section on dose)

Maximum dose: 0.1ml / 0.2ml / 0.5ml

Maximum number of vaccinations: Two doses

NB. Dosage is usually **1 Single Dose,**

However for children under 9 years of age and **if** receiving influenza vaccine for the first time, then 2 doses 4-6 weeks apart are given.

This differs for *Fluenz, Fluvirin, Enzira and CSL Influenza vaccine (split virion, inactivated), prefilled syringe by Pfizer.

- For Fluenz this applies **only** to those from **2 years to under 9 years old who are in a clinical at risk group.**
- For Fluvirin this applies only from **4 years to under 9 years.**
- For Enzira & CSL Influenza vaccine (split virion, inactivated), prefilled syringe (Pfizer): this applies to children aged **5 to 9 years old**.

(Please see Dosage/Dose range section above and refer to individual manufacturer's SPC for exact details).

*** (Please refer to Tripartite letter "The Flu immunisation programme 2013/14-extension to children," Page 6 - Gateway reference 00275. It states, "JCVI has advised that, when extending the flu immunisation programme to children, most children should be offered a single dose of the Fluenz®. However, children in clinical risk groups aged two to less than nine years who have not received flu vaccine before should be offered two doses of Fluenz® (given at least four week apart).**

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

- **CSL Inactivated influenza vaccine (by Pfizer vaccines) and Enzira®:**

  Have a higher rate of febrile convulsions in children under five years of age. Due to risk of febrile convulsions, these products are restricted to use in adults and children aged five years and older.

  These vaccines have an increased rate of fever in the age group five to under nine years. Clinicians should consider the use of alternative influenza vaccines authorised for use in children aged five to under nine years. If no suitable alternative vaccines are available, clinicians should ensure parents are aware of the risk and give clear advice on the management of vaccine-induced fever.

- **Viroflu® & Inflexal V®:**

  Have a higher rate of fever associated with use of the vaccine in children under five years old.

  Clinicians should consider the use of alternative seasonal influenza vaccines authorised for use in children under five years old. If no suitable alternative vaccines are available, clinicians should make parents aware of the risk and give clear advice about the management of post-vaccination fever in children and advised to monitor the child for fever for 2 - 3 days following vaccination.

- **Fluenz®:**

  There is a potential for transmission of live attenuated influenza virus in Fluenz to severely immunocomprimised contacts (e.g. bone marrow transplant patients requiring isolation) for one or two weeks following vaccination. Where close contact with immunocomprimised patients (for example household members) is likely or unavoidable, appropriate alternative inactivated influenza vaccines should be used. Please note, Fluenz is contraindicated in children and adolescents (<18yrs) receiving salicylate therapy, those with severe asthma (BTS SIGN step 4) or above, or those with active wheezing at the time of vaccination. Not to be given in pregnancy or breast feeding.

Potential Adverse Effects/Reactions: -

	Intramuscular Inactivated Influenza Vaccines (various brands)	Intradermal Inactivated Influenza Vaccine (Intanza ®)	Intranasal live attenuated influenza vaccine (Fluenz ®)
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.	Localised reactions and redness (redness may last up to 7 days). Induration, swelling, pain and pruritus. Headache, myalgia and malaise. Shivering and Fever.	Decreased appetite. Headache. Nasal congestion/ rhinorrhoea. Myalgia, pyrexia, malaise.
Uncommon Effects	See Individual SPC's	Paresthesia, , rash, arthralgia, and asthenia	Facial oedema, urticarial , epistaxis and rash.
Rarely	Anaphylaxis, neuralgia, convulsions. Transient thrombocytopenia. Paraesthesiae, vasculitis.	Sweating. Anaphylactic reaction.	Anaphylactic reaction.

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. All suspected ADR's occurring in children should be reported. 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 as appropriate

Reporting Procedure of Adverse Effects

- Report to doctor as 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 ADRs occurring in children should be reported. Please refer to www.mhra.gov.uk/yellowcard and Green Book- chapter 9 (20th March 2013).

See manufacturers Summary of Product Characteristics for details of all potential adverse reactions.

Advice to Patient/Carer (verbal or written)

- Explain protection level expected from vaccine.
- Provide a patient information leaflet and discuss as required.
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above and manufacturers SPC).
- Explain the "Out of Hours" procedure.
- Explain procedure for dealing with anaphylaxis /severe allergic reactions.
- Give date of next vaccine if applicable.
- Ensure patient-held vaccination record has been updated.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) as applicable.

Arrangements for Referral to Medical Advice

- Doctor appointment as and when appropriate

Records

In all cases manual records including computerised records and data collection for Child Health Information Services (CHIS) should include: -

- 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);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.

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.
- Store in a refrigerator (+2°C to +8°C). Discard if frozen.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline)
- **Please be aware of Resuscitation Council Guideline changes (2010)**

Special Considerations / Additional Information

- **Vaccines should be allowed to reach room temperature before use**; shake before use.
- The vaccine should be protected from light at all times, (exposure may inactivate the virus).
- Some influenza vaccines SPC indicate that young children can be given 0.25ml or a 0.5ml dose. The Joint Committee on Vaccination and Immunisation (JCVI) has advised that where these alternative doses are indicated in the SPC, the 0.5ml dose of intramuscular inactivated influenza vaccine should be given to infants aged six months or older and young children.
- **Fluenz® is the influenza vaccine of choice in the 2 and 3 year olds unless it is unsuitable.**
- **Fluenz® is the influenza vaccine of choice (unless it is unsuitable), for children aged 4 to 17 years who are in a clinical risk group category listed in Chapter 19 of the Immunisation Against Infectious Disease**: The Green Book. This is because Fluenz® provides greater protection for children than inactivated influenza vaccine.
- Other live attenuated vaccines, such as MMR, administered as part of the routine childhood immunisation programme can be given at the same time as Fluenz® or after a four week interval.
- There is no data on the concurrent use of Fluenz® with antiviral agents active against influenza but these are likely to reduce the effectiveness of Fluenz® if given within 48 hours before or two weeks after vaccination
- Children and adolescents younger than 18 years of age: Do not administer Fluenz® if receiving salicylate therapy and do not use salicylates for 4 weeks after vaccination.
- Vaccine recipients should be informed that FLUENZ is an attenuated live virus vaccine and has the potential for transmission to immunocompromised contacts. Vaccine recipients should attempt to avoid, whenever possible, close association with severely immunocompromised individuals (e.g. bone marrow transplant recipients requiring isolation) for 1-2 weeks following vaccination.
- Enzira and CSL Biotherapies generic influenza vaccines marketed by Pfizer should be used with caution in children aged five to less than nine years.
- Due to the risk of high fever with Viroflu & Inflexal-V, consideration should be given to the use of alternative seasonal influenza vaccines in children under the age of 5 years. In case it is used in children, parents should be advised to monitor for fever for 2 - 3 days following vaccination."
- **Pregnant women** should be vaccinated, regardless of the stage of pregnancy. There is no evidence of risk from vaccinating women or those who are breast-feeding with inactivated virus vaccines.

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Management & Monitoring of Patient Group Direction NECSAT 2013/005

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 Patient Group Direction by named healthcare professionals.

- Please retain this original PGD & form for future photocopying and use.
- This PGD is to be read, agreed to and signed by all registered healthcare professionals it applies to.
- 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 give

INFLUENZA VACCINE (Seasonal Flu Vaccine)

.....under this PGD

(By signing this document, the healthcare professional is stating that they are competent to work under this PGD & accept full clinical responsibility for any decisions made with using this PGD).

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

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

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from: 9th Sept. 2013	Review Date: - July 2015	**Expiry Date: - 8th September 2015**

Patient Group Direction (PGD) for the Administration of

ADRENALINE (Epinephrine) INJECTION For The TREATMENT of ANAPHYLAXIS

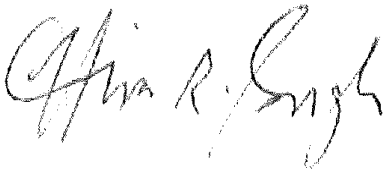
by Community Pharmacists to Individuals Accessing NHS Services from Commissioned and Accredited Community Pharmacies in Cumbria, Northumberland, Tyne & Wear.

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

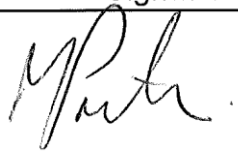
Direction Number: - **NECSAT 2013/007**

Valid from:	23rd September 2013
Review date:	1st July 2015
Expiry date:	**22nd September 2015**

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)*		7/10/2013
Consultant Public Health Medicine (Public Health England, Durham, Darlington & Tees)	**Dr Malathi Natarajan** *(Senior Doctor)*		7/10/2013

This PGD has been approved for use in Cumbria, Northumberland, Tyne& Wear by: –

Title	Name	Signature	Date
Medical Director (Cumbria, Northumberland, Tyne& Wear)	**Dr Mike Prentice** *(Governance Authorisation)*		10/10/13.

1. 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 Pharmacists: - General Pharmaceutical Council (GPhC)

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.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and latest *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 completion of an accredited 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.

2. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

- Patients in whom an anaphylactic reaction is identified.

Objectives of care: To treat anaphylaxis and to preserve life

Inclusion criteria

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

Emergency treatment of acute anaphylaxis

All who treat anaphylaxis should be aware of the potential for confusion between anaphylaxis and syncope and panic attacks.

First Line Management

1) **Call for emergency ambulance immediately** & follow the standard **ABCDE rule -** **Airways**
   Breathing
   Circulation
2) Secure and maintain airways — Disability
3) Restore blood pressure (lay patient flat and elevate feet). — Exposure

   (NB. Patients with Airway and Breathing problems may prefer to sit up, as this will make breathing easier).

Please also refer to **Appendix 1** for additional information on recognition of anaphylactic reactions.

Please also refer to **Appendix 2** for additional information on basic life support

Exclusion criteria

- Previous allergy to adrenaline.
- Other contra-indications are relative as adrenaline is being administered in an emergency situation.

Refer to current SPC &/or BNF for full list of details.

Action if excluded

- Call 999 Emergency services and/or refer to doctor as appropriate. Ensure all actions/decisions are documented.

Action if patient declines treatment

Not considered likely but: -

- Ensure patient, parent or guardian fully understands risks of declining treatment.
- Call 999 Emergency services and/or refer to doctor as appropriate.
- Document refusal and advice given in medical notes (written or electronic).

3. Description of Treatment.

Name, strength & formulation of drug:

Adrenaline (epinephrine)	**1mg/1ml**	(1 in 1000)	solution for injection	ampoules
Adrenaline (epinephrine)	**500mcg/0.5ml**	(1 in 1000)	solution for injection	ampoules
Adrenaline (epinephrine)	**500mcg/0.3ml**	(1 in 1000)	solution for inj. (pre-filled syringe)	auto-injector
Adrenaline (epinephrine)	**300mcg/0.3ml**	(1 in 1000)	solution for inj. (pre-filled syringe)	auto-injector
Adrenaline (epinephrine)	**150mcg/0.3ml**	(1 in 2000)	solution for inj. (pre-filled syringe)	auto-injector

Legal Status:

POM – Prescription Only Medicines

(NB. POM restriction does not apply to adrenaline injection 1mg/ml where administration is for saving life in emergency)

Dosage/Dose range:

The dose regime of intramuscular adrenaline 1 in 1000 (1mg/ml)

Adults (18 years old and over)	**500 micrograms (or 0.5mg) = 0.5ml** (If patient is small use **300 micrograms (or 0.3mg))**
	300 micrograms (or 0.3mg) This dose should only be used if: - • The adult patient is small, or • A 500mcg solution for injection is unavailable for administration
• **Repeat the IM adrenaline dose if there is no improvement in the patient's condition.** • **Further doses can be given at about 5-minute intervals according to the patient's response.**	

- The solution for injection (ampoules) should only be used where the healthcare professional is competent to do so.
- Auto-injectors for self-administration of adrenaline should not be used as a substitute for a proper anaphylaxis pack. However, if an adrenaline auto-injector is the only available adrenaline preparation when treating anaphylaxis, health care providers should use it.

Route/Method: -

Intra-muscular (IM) injection (preferably mid-point in anterolateral thigh)

Frequency of Administration:

If no improvement occurs in patient's condition, **dose may be repeated if necessary at 5-minute intervals**, according to blood pressure, pulse and respiratory function.

Maximum dose: **500mcg**

Maximum number of treatments: **No limit –** (determined by patient response)**

**(For additional information, refer to the Resuscitation Guidance (UK) (2008), *Emergency treatment of anaphylactic reactions – Guidelines for healthcare providers*).

Follow up treatment: -

- **Dial 999** for immediate referral to Accident & Emergency for assessment and observation

4. Further Aspects of Treatment:

Relevant Warnings & Potential Adverse Effects & Reporting

*Potential Adverse Effects: -

- Anxiety, nausea, tremor, sweating, tachycardia, vomiting, headache, dizziness, cold extremities and dyspnoea

*Reactions/Interactions: -

- Patients taking tricyclic antidepressants are more susceptible to arrythmias;
- Non-selective beta-blockers e.g. propranolol – may cause severe hypertension and bradycardia.

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ drugs 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).

*See manufacturers Summary of Product Characteristics &/or BNF for details of all potential adverse effects and reactions.

Identification and Management of Adverse Reactions

- See anaphylaxis guidelines. Patient/Parent/Guardian requested to report side effects
- Refer to doctor or other service as appropriate

Advice to Patient/Carer (verbal or written)

- To report this reaction before any future medical or dental treatment. / Carry Medic-Alert (or similar).

Arrangements for Referral to Medical Advice

- Doctor or ambulance to attend as soon as possible, (whichever is the most appropriate).
- Paramedics to attend if severe / no response to treatment.

Records

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

- Patient's name and date of birth; - Confirmation that there are no contraindications;
- Reason adrenaline is required; - Dose/amount of adrenaline administered;
- Site & route of injection; - Time & date of administration;
- Brand name (if applicable), batch number and expiry date of injection
- Whom administered by and signature of person administering injection (if not recorded on computer).
- Cause of reaction; - Support literature given (as applicable).
- Advice given to patient; - Outcome (e.g. referral to hospital).
- Any further details as required by the Service Level Agreement (SLA)

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.
- Hand washing facilities/equipment is readily available.
- Stock control & storage/disposal of vaccines/injections in accordance with standard practice / protocols/ guidelines.
- Immediate access to Epinephrine (Adrenaline) injection (as a minimum). (Please refer to PGD for adrenaline).
- Any additional requirements as details in the SLA
- Do not store above 25º C
- Stock control & storage of vaccines in accordance with local policies / protocols/ guidelines.

Special Considerations / Additional Information

- **Patients having an anaphylactic reaction should be recognised and treatment should be based on general life support principles: -**
  - Use the Airway, Breathing, Circulation, Disability and Exposure (ABCDE) approach to recognise and treat problems.
  - Call for help early.
  - Treat the greatest threat to life first.
  - Initial treatments should not be delayed by the lack of a complete history or definite diagnosis.

- **Patients having an anaphylactic reaction in any setting should expect the following as a minimum: -**
  - Recognition that they are seriously unwell.
  - An early call for help.
  - Initial assessment and treatments based on an ABCDE approach, (see Appendix 2).
  - Adrenaline therapy if indicated.
  - Investigation and follow-up by an allergy specialist.

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Management & Monitoring of Patient Group Direction NECSAT 2013/007

The Administration of

ADRENALINE (Epinephrine) INJECTION

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

- Please retain this original PGD & form for future photocopying and use.
- This PGD is to be read, agreed to and signed by all registered healthcare professionals it applies to.
- 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 give

ADRENALINE (Epinephrine) INJECTION (via suitable delivery device)

……under this PGD

(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:23rd Sept. 2013	Review Date: - July 2015	**Expiry Date: - 22nd September 2015**

Appendix 1.

Recognition of an Anaphylactic Reaction (summarised)

(Please refer to the Resuscitation Council (UK) January 2008 guidelines on "Emergency Treatment of Anaphylactic Reactions" for the full & complete guidance)

Definition of Anaphylaxis

A severe, life-threatening, generalised or systemic hypersensitivity reaction, characterised by rapidly developing life-threatening airway and/or breathing and/or circulation problems usually associated with skin and mucosal changes.

When recognising and treating any acutely ill patient: -

- ABCDE approach must be followed (see also Refer to Resuscitation Council UK for more information) &
- Life threatening problems treated as they are recognised.

Anaphylaxis is likely when all of the following 3 criteria are met: -

1) **Sudden onset and rapid progression of symptoms**
2) **Life-threatening Airway and/or Breathing and/or Circulation problems**
3) **Skin and/or mucosal changes (flushing, urticaria, angioedema)**

The following supports the diagnosis: -

- Exposure to a known allergen for the patient

Remember: -

- Skin or mucosal changes alone are not a sign of an anaphylactic reaction
- Skin and mucosal changes can be subtle or absent in up to 20% of reactions (some patients can have only a decrease in blood pressure, i.e. Circulation problem)
- There can be gastrointestinal symptoms (e.g. vomiting, abdominal pain, incontinence).

1) Sudden onset and rapid progression of symptoms

- The patient will feel and look unwell.
- Most reactions occur over several minutes. Rarely, reactions may be slower in onset.
- The time of onset of an anaphylactic reaction depends on the type of trigger.
- An intravenous trigger will cause a more rapid onset of reaction than stings which, in turn, tend to cause a more rapid onset than orally ingested triggers.
- The patient is usually anxious and can experience a "sense of impending doom".

2) Life threatening Airways &/or Breathing &/or Circulation problems

Patients can have either an A or B or C problem or any combination. Use the ABCDE approach to recognise these.

Airway problems:

- Airway swelling, e.g., throat and tongue swelling (pharyngeal/laryngeal oedema).
- The patient has difficulty in breathing and swallowing and feels that the throat is closing up.
- Hoarse voice.
- Stridor – this is a high-pitched inspiratory noise caused by upper airway obstruction.

Breathing problems:

- Shortness of breath increased respiratory rate.
- Wheeze
- Patient becoming tired.
- Confusion caused by hypoxia.
- Cyanosis (appears blue) –this is usually a late sign.
- Respiratory arrest.

Circulation problems:

- Signs of shock –pale, clammy.
- Increased pulse rate (tachycardia).
- Decreased conscious level or loss of consciousness.
- Hypotension – feeling faint (dizziness), collapse.
- Anaphylaxis can cause myocardial ischaemia and electrocardiograph (ECG) changes even in individuals with normal coronary arteries.
- Cardiac arrest

The above Airway, Breathing and Circulation problems can all alter the patient's neurological status (**Disability problems**) because of decreased brain perfusion. There may be confusion, agitation and loss of consciousness.

3) Skin and/or mucosal changes

These should be assessed as part of the **Exposure** when using the ABCDE approach.

- They are often the first feature (present in >80% of anaphylactic reactions).
- Can be subtle and dramatic
- There may be just skin, just mucosal, or both skin and mucosal changes.
- There may be erythema – patchy, or generalised, red rash.
- There may be urticaria (also called hives, nettle rash, weals or welts), which can appear anywhere on body. The weals may be pale, prink or red and may look like nettle stings. They can be different shapes and sizes and are often surrounded by a red flare. They are usually itchy.
- Angioedema is similar to urticaria but involves swelling of deeper tissues, most commonly in the eyelids, lips and sometimes in the mouth and throat

NB. Skin changes without life-threatening airway, breathing or circulation problems do not signify an anaphylactic reaction.

Differential diagnosis

Life-threatening conditions

- Sometimes an anaphylactic reaction can present with symptoms and signs that are very similar to life-threatening asthma – this is commonest in children
- A low blood pressure (or normal in children) with a petechial or purpuric rash can be a sign of septic shock.
- Seek help early if there are any doubts about the diagnosis and treatment.
- Following an ABCDE approach will help with treating the differential diagnosis.

Non-life-threatening conditions (these usually respond to simple measures)

- Faint (vasovagal episode).
- Panic attack.
- Breath-holding episode in child.
- Idiopathic (non-allergic) urticaria or angioedema

There can be confusion between an anaphylactic reaction and a panic attack.

Panic attack symptoms may resemble anaphylaxis in some ways: -

- The sense of impending doom and breathlessness leading to hyperventilation.
- There may sometimes be flushing or blotchy skin associated with anxiety, but there is no hypertension, pallor, wheeze, or urticarial rash or swelling.
- Vasovagal attacks post immunisation procedures, but the absence of rash, breathing difficulties and swelling are useful distinguishing features.
- Slow pulse of a vasovagal attack compared with the rapid pulse of a severe anaphylactic episode.
- Fainting usually responds to lying patient down and raising legs.

Underlying Principles to note: -

The approach to all critically ill patients, including those who are having an anaphylactic reaction, is the same.

The underlying principles are: -

1. Use an Airway, Breathing, Circulation, Disability, and Exposure (the ABCDEs) approach to assess and treat the patient.
2. Do a complete initial assessment and re-assess regularly.
3. Treat life-threatening problems before moving to the next part of assessment.
4. Assess the effects of treatment.
5. Call for help early (e.g., calling for an ambulance or resuscitation team).
6. Use all members of the team or helpers. This will enable interventions, e.g., calling for help, assessment, attaching monitoring equipment, and intravenous access, to be undertaken simultaneously.
7. Communicate effectively.
8. The aim of the initial treatments is to keep the patient alive, and achieve some clinical improvement. This will buy time for further treatment and expert help.
9. Remember - it can take a few minutes for treatments to work.
10. The ABCDE approach can be used irrespective of your training and experience in clinical assessment or treatment. The detail of your assessment and what treatments you give will depend on your clinical knowledge and skills. If you recognise a problem or are unsure, call for help.

Patients with Airway and Breathing problems may prefer to sit up as this will make breathing easier.
• Lying flat with or without leg elevation is helpful for patients with a low blood pressure (Circulation problem). If the patient feels faint, do not sit or stand them up - this can cause cardiac arrest.32
• Patients who are breathing and unconscious should be placed on their side (recovery position).
• Pregnant patients should lie on their left side to prevent caval compression.35

Appendix 2.

Adult Basic Life Support

(Please refer to the Resuscitation Council (UK) October 2010 Resuscitation Guidelines for full details

Adult Basic Life Support Sequence

Basic life support consists of the following sequence of actions:

1. Make sure the victim, any bystanders, and you are safe.

2. Check the victim for a response.

- Gently shake his shoulders and ask loudly, **'Are you all right?'**

3A. If he responds:

- Leave him in the position in which you find him provided there is no further danger.
- Try to find out what is wrong with him and get help if needed.
- Reassess him regularly.

3B. If he does not respond:

- Shout for help.
- Turn the victim onto his back and then open the airway using head tilt and chin lift:
    - Place your hand on his forehead and gently tilt his head back.
    - With your fingertips under the point of the victim's chin, lift the chin to open the airway.

4. Keeping the airway open, look, listen, and feel for normal breathing.

- Look for chest movement.
- Listen at the victim's mouth for breath sounds. - Feel for air on your cheek.

In the first few minutes after cardiac arrest, a victim may be barely breathing, or taking infrequent, noisy, gasps. This is often termed agonal breathing and must not be confused with normal breathing.

Look, listen, and feel for **no more** than **10 s** to determine if the victim is breathing normally. If you have any doubt whether breathing is normal, act as if it is **not** normal.

5A. If he is breathing normally:

- Turn him into the recovery position (**see below**).
- Summon help from the ambulance service by mobile phone. If this is not possible, send a bystander. Leave the victim only if no other way of obtaining help is possible.
- Continue to assess that breathing remains normal. If there is any doubt about the presence of normal breathing, start CPR (5B).

5B. If he is not breathing normally:

- Ask someone to call for an ambulance and bring an AED if available. If you are on your own, use your mobile phone to call for an ambulance. Leave the victim only when no other option exists for getting help.
- Start chest compression as follows:
    - Kneel by the side of the victim.
    - Place the heel of one hand in the centre of the victim's chest (which is the lower half of the victim's sternum (breastbone)).
    - Place the heel of your other hand on top of the first hand.
    - Interlock the fingers of your hands and ensure that pressure is not applied over the victim's ribs. Do not apply any pressure over the upper abdomen or the bottom end of the sternum.

- Position yourself vertically above the victim's chest and, with your arms straight, press down on the sternum 5 - 6 cm.
- After each compression, release all the pressure on the chest without losing contact between your hands and the sternum. Repeat at a rate of 100 - 120 min-1.
- Compression and release should take an equal amount of time.

6A. Combine chest compression with rescue breaths:

- After 30 compressions open the airway again using head tilt and chin lift.
- Pinch the soft part of the victim's nose closed, using the index finger and thumb of your hand on his forehead.
- Allow his mouth to open, but maintain chin lift.
- Take a normal breath and place your lips around his mouth, making sure that you have a good seal.
- Blow steadily into his mouth whilst watching for his chest to rise; take about one second to make his chest rise as in normal breathing; this is an effective rescue breath.
- Maintaining head tilt and chin lift, take your mouth away from the victim and watch for his chest to fall as air comes out.
- Take another normal breath and blow into the victim's mouth once more to give a total of two effective rescue breaths. The two breaths should not take more than 5 s. Then return your hands without delay to the correct position on the sternum and give a further 30 chest compressions.
- Continue with chest compressions and rescue breaths in a ratio of 30:2.
- Stop to recheck the victim only if he starts to show signs of regaining consciousness, such as coughing, opening his eyes, speaking, or moving purposefully AND starts to breathe normally; otherwise **do not interrupt resuscitation.**

If the initial rescue breath of each sequence does not make the chest rise as in normal breathing, then, before your next attempt:

- Check the victim's mouth and remove any visible obstruction.
- Recheck that there is adequate head tilt and chin lift.
- Do not attempt more than two breaths each time before returning to chest compressions.

If there is more than one rescuer present, another should take over CPR about every 1-2 min to prevent fatigue. Ensure the minimum of delay during the changeover of rescuers, and **do not interrupt chest compressions.**

6B. Compression-only CPR

- If you are not trained to, or are unwilling to give rescue breaths, give chest compressions only.
- If chest compressions only are given, these should be continuous at a rate of 100 - 120 min-1.
- Stop to recheck the victim only if he starts to show signs of regaining consciousness, such as coughing, opening his eyes, speaking, or moving purposefully AND starts to breathe normally; otherwise **do not interrupt resuscitation.**

7. Continue resuscitation until:

- qualified help arrives and takes over,
- the victim starts to show signs of regaining consciousness, such as coughing, opening his eyes, speaking, or moving purposefully AND starts to breathe normally, OR
- you become exhausted.

Further points related to basic life support - Risks to the rescuer and victim

The safety of both the rescuer and victim are paramount during a resuscitation attempt.
There have been few incidents of rescuers suffering adverse effects from undertaking CPR, with only isolated reports of infections such as tuberculosis (TB) and severe acute respiratory distress syndrome (SARS). Transmission of HIV during CPR has never been reported. There have been no human studies to address the effectiveness of barrier devices during CPR; however, laboratory studies have shown that certain filters, or barrier devices with one-way valves, prevent transmission of oral bacteria from the victim to the rescuer during mouth-to-mouth ventilation. Rescuers should take appropriate safety precautions where feasible, especially if the victim is known to have a serious infection such as TB or SARS. During an outbreak of a highly infectious condition (such as SARS), full protective precautions for the rescuer are essential.