Patient Group Direction (PGD) for the Administration of

INFLUENZA (Seasonal Flu) Vaccines

by Registered Professionals to Individuals Accessing NHS Services in
Durham, Darlington, Tees (DDT) and Cumbria, Northumberland, Tyne & Wear (CNTW)

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

Direction Number: - **NECSAT 2014/011**
Valid from: 1st September 2014
Review date: 1st June 2016
Expiry date: 31st August 2016

This patient group direction has been developed & produced by: -			
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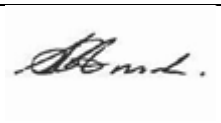
Immunisation and Screening Manager (Public Health England, DDT)	**Sandra Ansah** *(Senior Nurse)*		22/08/2014

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)*		/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)*		03/09/14

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 (PHE) Green Book Guidance – Influenza chapter 19 (July 14))

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 reference 2013521, Annex A to D.

- **All those aged 65 years and over** (i.e. those aged 65yrs on or before 31/03/15 (born before or on 31/03/1950)).
- **Children aged 2, 3 and 4 years** (but not 5 years or older) on or before 1st September 2014).
- **School-aged children who are part of the pilot childhood programme** being run within geographical pilot sites.
- **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 atresia & chronic hepatitis).
  e) **Chronic neurological disease** (Stroke and TIA. Conditions in which respiratory function may be compromised (e.g. polio syndrome).
  f) **Diabetics** (Type 1 diabetics; Type 2 diabetics requiring insulin or oral hypoglycaemic drugs; diet controlled diabetics).
  g) **Immunosuppression due to disease or treatment (see precautions & exclusions on live attenuated vaccines).** 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).
- **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. (This 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 healthcare** such that they & vulnerable patients are at increased risk of exposure to seasonal flu.

Exclusion criteria (Refer to current SPC and Green Book Guidance (Online version) for additional details)

General exclusions

- No valid consent; ● Under 6 months of age; ● Healthy children that turn 2 years old after 01/09/2014
- Patient is acutely unwell. 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 the influenza vaccine.
- Confirmed anaphylactic reaction to any component, ingredient, or excipient of the influenza vaccine.
- Confirmed anaphylaxis to egg or those with egg allergy + severe uncontrolled asthma (refer to specialist)
- Hypersensitivity to any excipient or residue listed within the vaccine's SPC or product information. See also Precautions section.
- Hypersensitivity to formaldehyde, chicken protein & 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 immunised in primary care using an inactivated influenza vaccine with an ovalbumin content of less than 0.12mcg/ml (i.e. containing < 0.06mcg per 0.5ml dose).

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

Refer to individual SPC for full list of reactions and contraindications. See also "Relevant Warnings" section of this PGD.

- For CSL *Inactivated Influenza Vaccine* (Split Viron) Ph.Eur. (Pfizer & MASTA) **- children aged under 5 years.**
- For *Enzira* - **children aged under 5 years.**
- For Fluarix Tetra - **children less than 3 years old**.
- For Intanza (15mcg/strain) - **Individuals under 60 years old.**
- For Intanza (9mcg/strain) - **adults 60 years old and over;** **- children under 18 years old.**
- For Optaflu (Novartis) - **individuals under 18 years old.**

For Fluenz Tetra

- children less than 24 months old. ● children 18years old and over. ● pregnancy & breast feeding.
- children aged 5 to 17 years old who are **not in a clinical risk group category** listed in Chapter 19 – Influenza (The Green Book , July 2014) or who are **not in a pilot childhood programme** being run within geographical pilot sites.
- those children and adolescents under 18 years of age receiving salicylate therapy.
- those who are clinically severely immuno-deficient due to conditions or immunosuppressive therapy such as:
  - acute & chronic leukaemias; lymphoma; HIV infection not on highly active antiretroviral therapy (HAART);
  - cellular immune deficiencies;

  (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 on-line Green Book, Chapter 19).
- individuals with any degree of egg allergy. NB. There is no data on use of Fluenz® Tetra in children with egg allergy.
- children with a history of active wheezing at the time of vaccination (until at least 7 days after wheezing has stopped).
- Those who are currently taking or have been prescribed oral steroids in the last 14 days.
- Those who are currently taking a high dose inhaled steroid – Budesonide >800mcg/day or equivalent*

  (E.g. Fluticasone >500mcg/day) because of limited safety data in these groups.

  ***** (in children aged 5-12 years, the definition of severe asthma corresponds to the British Thoracic Society BTS Sign Step 5).
- Not to be given concomitantly with antivirals (delay vaccination until 48hrs after treatment cessation with antiviral agents).
- **Temporary Exclusion -** Administration of Fluenz® should be postponed if suffering from heavy nasal congestion. This is because heavy congestion may impede delivery of the vaccine to the nasopharyngeal mucosa.

Precautions

- Patients with egg allergy 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 then, patients should be immunised in primary care using an inactivated influenza vaccine with ovalbumin content less than 0.12mcg/ml (equivalent to 0.06mcg per 0.5ml dose). Only patients with a confirmed anaphylaxis to egg or with egg allergy and severe uncontrolled asthma should be referred to specialists for immunisation in hospital
- Optaflu is only suitable for those aged 18yrs old and over. Refer to Section 2 (page 5) for products with low ovalbumin content.
- Hypersensitivity reactions to previous dose of vaccine or component, ingredient or excipient of vaccine:
  - **NB**. "Local adverse reactions that generally start within a few hours of the injection are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens"

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.

Circumstances in which further advice should be sought from doctor and/or specialist

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

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

Action if patient declines treatment

- Ensure patient/parent/guardian fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications.
- Give advice about the disease, how to recognise it and action required if suspected.
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate.

2. Description of Treatment.

Name, strength & formulation of drug

- **Inactivated Influenza Vaccine 0.5ml & 0.25ml Pre-filled Syringe (PFS);**
- **Live Attenuated Influenza Vaccine (LAIV) as a 0.2ml / dose Nasal Spray**

Table 1 - Influenza vaccines available for 2014/15 national influenza immunisation programme are: -

Supplier	Name of product	Vaccine Type	Age indications	Ovalbumin content (µg/ dose)
Abbott Healthcare	**Influvac sub-unit ®**	Trivalent Surface antigen, inactivated sub-unit	**From 6 months**	0.1mcg / 0.5ml dose
	Imuvac®			
AstraZeneca UK Ltd	**FLUENZ® Tetra ▼**	Quadrivalent Live, attenuated (Nasal spray susp.)	**From 24 months** to less than 18yrs of age	≤ 0.24mcg / 0.2ml dose
GlaxoSmithKline	**Fluarix ™ Tetra ▼**	Quadrivalent Inactivated virus	**From 3 years**	≤ 0.05mcg / 0.5ml dose
MASTA	**Imuvac®**	Trivalent inactivated	**From 6 months**	0.1mcg / 0.5ml dose
	Enzira® †	Trivalent, Inactivated split virion	**From 5 years**	≤ 1mcg / 0.5ml dose
	Inactivated influenza vaccine (Split Virion) BP	Trivalent Inactivated virus	**From 6 months**	≤ 0.05mcg / 0.5ml dose
	Influvac sub-unit ®	Trivalent Inactivated	**From 6 months**	0.1mcg / 0.5ml dose
	CSL Inactivated Influenza † vaccine		**From 5 years**	≤ 1.0mcg / 0.5ml dose
Novartis Vaccines	**Agrippal®**	Trivalent, Inactivated	**From 6 months**	≤ 0.2mcg / 0.5ml dose
	Optaflu® ▼	Trivalent, inactivated. Prepared in cell culture	**From 18 years**	**No ovalbumin**
Pfizer Vaccines	**CSL Inactivated Influenza † vaccine** (Split Virion) **Ph.Eur**	Trivalent Inactivated, split virion,	**From 5 years**	≤ 1.0mcg / 0.5ml dose
	Enzira® †			
Sanofi Pasteur MSD	**Inactivated influenza vaccine BP**	Trivalent, Inactivated, split virion,	**From 6 months**	≤ 0.05mcg / 0.5ml dose
	Intanza® 9mcg	Trivalent, 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). (Please refer to relevant SPCs & Green Book Chapter 19 - Influenza).

None of the influenza vaccines for 2014/15 season contain thiomersal as an added preservative.

† There are an increased number of reports of fever in the age group 5 to less than 9 years with these vaccines.

Legal Status:

POM –Prescription Only Medicine

Dosage/Dose range:

Children aged 6 months to less than 2 years of age IN clinical risk groups:

- Offer 1 dose of a suitable inactivated trivalent vaccine
- Those not previously vaccinated, a 2nd dose should be given after an interval of at least 4 weeks after the 1st dose in accordance with the manufacturer's SPC. (NB. Inactivated vaccines are interchangeable).

Children aged 2 to 17 years of age IN clinical risk groups:

- Offer 1 dose of Fluenz Tetra® (unless unsuitable - see exclusions & precautions sections).
- Fluenz® Tetra is the vaccine of choice for children in clinical risk groups aged 2-17 years
- Those not previously vaccinated & aged between 2 and under 9 years should be offered a 2nd dose at least 4 weeks later.
- For those children for whom Fluenz Tetra® is unsuitable, a suitable inactivated influenza vaccine should be offered. NB. The quadrivalent inactivated influenza vaccine (Fluarix™ Tetra) is only authorised for children aged three years and older.
- Children aged less than nine years who have not received inactivated influenza vaccine previously should be offered a second dose of vaccine, at least four weeks after the first dose.

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 & Green Book Chart on page 7

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 Table 1)	Single injection of **0.5ml** Children aged 6 months to less than 9 years who have not received influenza vaccine before should receive a 2nd dose of vaccine at least 4 weeks later.	Inactivated intramuscular vaccines. **Brands include:** Agrippal® , Enzira® , Fluarix® Tetra, Imuvac®, Influvac Sub-unit ®, Inactivated influenza vaccine BP (by Sanofi Pasteur MSD), Inactivated influenza vaccine (Split Virion) BP (by MASTA)
Children aged 2 to 17 years old • Children aged 2, 3 and 4 years. • Children aged 2 to 17 years in a clinical at risk group category • School aged children as part of the pilot childhood programme.	Application of one single **0.2ml** dose (administered as 0.1ml in each nostril) * Children **NOT in clinical risk groups** only require one single 0.2ml dose of Fluenz Tetra (administered as 0.1ml per nostril). * Children in clinical risk groups aged two to less than 9 years who have not received an influenza vaccine before should receive a 2nd dose of vaccine at least 4 weeks later.	Live attenuated intranasal vaccine. **Fluenz® Tetra ▼** nasal spray suspension (Fluenz® Tetra 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 ▼**
5 years old and over	Single injection of **0.5ml**	**Enzira®** **CSL Inactivated Influenza vaccine**
18 years old and over	Single injection of **0.5ml**	**Optaflu® ▼**
Adults aged 18yrs to 59yrs 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 "The national childhood flu immunisation programme 2014/15-Information for healthcare professionals, page 8: (Gateway no. 2014 - 245). 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.

Figure 1 - Green Book Chart summarising advice for 2014/15 influenza vaccination programme

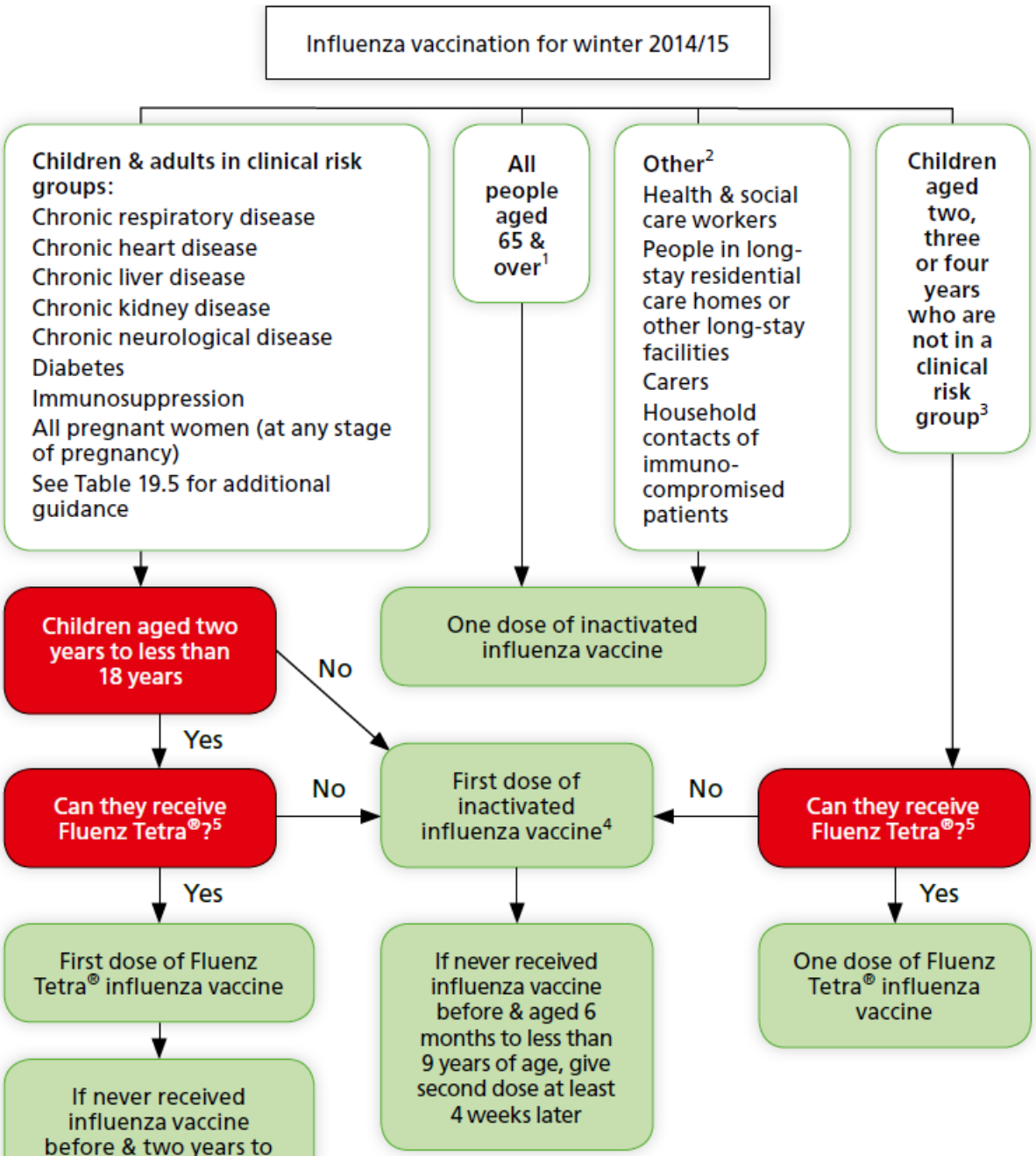


Figure 19.2: Chart summarising the advice on influenza vaccination for the 2014/15 influenza vaccination programme. This chart should be read in conjunction with the contraindications and precautions sections and also Table 19.6 that gives details about the age indications for influenza vaccines.

1 all those aged 65 years or older including all those aged 65 years on or before 1 March 2015

2 follow additional guidance from UK health departments

3 all children aged two three or four years (but not five years or older) on or before 1 Sept 2014*

4 if quadrivalent inactivated vaccine available, consider for **children age three years and older only.**
If quadrivalent unavailable, offer suitable trivalent inactivated influenza vaccine. See table 19.6 which lists the vaccines that can be used in young children - **some are not suitable for young children.**

5 cannot receive if: under age of two years; 18 years and older; have egg allergy; a history of active wheezing at the time of vaccination (until at least 7 days after wheezing has stopped); on oral steroids or high dose inhaled steroids for asthma; certain immunodeficiencies; or pregnant. see contraindications and precautions for full list and details

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® Tetra** (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 equivalent to **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: (Refer to PHE Green Book Guidance (July 2014) for additional details)

Annual - (see also section on dose)

Maximum dose / Maximum number of vaccinations:

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 Tetra, Enzira and CSL Influenza vaccine (split virion, inactivated), prefilled syringe by Pfizer.

- For Fluenz Tetra this applies **only** to those from **2 yrs to under 9 years old who are in a clinical at risk group.**
- 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 "The national childhood flu immunisation programme 2014/15-Information for healthcare professionals, page 8: (Gateway no. 2014 - 245).**

The JCVI has advised that, 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:

As above and as per current PHE Green Book recommendations (see also figure 1, page 7)

3. 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 / by MASTA) 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.
- **Fluenz® Tetra:**
  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 refer to exclusion criteria for Fluenz Tetra.

Potential Adverse Effects/Reactions: -

	Intramuscular Inactivated Influenza Vaccines (various brands)	**Intradermal Inactivated Influenza Vaccine (Intanza ®)**	**Intranasal live attenuated influenza vaccine (Fluenz Tetra)**
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.
  See Manufacturers SPC for full details of all potential adverse reactions.

Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- **Advice on management including anaphylaxis**: - Chapter 8 of the Green Book provides detailed advice on managing ADRs following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor if appropriate. **Please be aware of Resuscitation Council Guideline changes (2010)**

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

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All suspected Adverse drug reactions to vaccines occurring in children, or in individuals of any age after vaccines labelled with a black triangle (▼), should be reported to the MHRA using the yellow card scheme.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and the on-line Green Book- Chapter 9.

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 procedure for dealing with anaphylaxis /severe allergic reactions. Explain the "Out of Hours" procedure.
- 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) if applicable.

Arrangements for Referral to Medical Advice

- Doctor appointment as and when appropriate

Records

In all cases manual records including the Personal Held Child Record, 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 & expiry date of vaccine;
- Whom administered by & signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed; Support literature given (if applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.

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. Have access to a telephone.
- 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 as applicable)
- **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).
- Individuals who have immunosuppression and HIV infection (regardless of CD4 count) should still be given influenza vaccine in accordance with recommendations and exclusions above. These individuals may not make a full antibody response.
- Live attenuated influenza vaccine (Fluenz Tetra®) has been purchased centrally for children aged two, three and four years and for children aged two to 17 years in risk groups. For both healthy and at risk children under 18 years of age where Fluenz is unsuitable an inactivated trivalent vaccine (Sanofi Pasteur MSD Split Virion BP) or Fluarix™ Tetra will be supplied.
- 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® Tetra is the influenza vaccine of choice in all 2, 3 and 4 year olds unless it is unsuitable.**
- **Fluenz® Tetra is the influenza vaccine of choice (unless it is unsuitable), for children aged 5 to 17 years who are in a clinical risk group category listed in Chapter 19 of the Immunisation Against Infectious Disease (**The Green Book). Fluenza Tetra provides greater protection for children than inactivated influenza vaccine.
- **Fluenz Tetra is the influenza vaccine of choice (unless it is unsuitable), for school-aged children who are part of the pilot childhood programme** being run within geographical pilot sites.
- 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® Tetra.
- There is no data on the concurrent use of Fluenz® Tetra with antiviral agents active against influenza but these are likely to reduce the effectiveness of Fluenz® Tetra if given within 48 hours before or two weeks after vaccination
- Children and adolescents younger than 18 years of age: Do not administer Fluenz® Tetra if receiving salicylate therapy and do not use salicylates for 4 weeks after vaccination.
- Vaccine recipients should be informed that FLUENZ TETRA 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 & CSL Biotherapies generic influenza vaccines should be used with caution in children aged 5 to < 9 years**.**
- **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.

(Please see updated Green Book – Online version, Chapter 19 (July 2014) and the manufacturer's SPC)

References

- ***NHS Executive HSC 2000/026*** (9th August 2000): Patient Group Directions [England only].
- ***Department of Health (DH) & Public Health England (PHE) & NHS England Letter***: The flu immunisation programme 2013/14 (05/06/13): Publication Gateway Reference Number 00157.
- ***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 (PHE).*** The national childhood flu immunisation programme 2014/15 **-** Information for healthcare practitioners (August 2014): PHE publications gateway number: 2014 - 245.
- ***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.
- ***British National Formulary (BNF)***, current edition. Available at http://www.bnf.org/bnf/index.htm
- ***Nursing and Midwifery Council (NMC), 2007***: Standards for Medicines Management.
- ***Nursing and Midwifery Council (NMC), 2007***: Record Keeping Advice Sheet.
- ***Nursing and Midwifery Council (NMC), 2008***: Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- ***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).
- AstraZeneca UK Ltd, Fluenz ® Tetra ▼ - ***Summary of Product Characteristics***, 19/08/14 (accessed from Electronic Medicines Compendium on 20/08/14).
- 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).
- Sanofi Pasteur MSD Ltd., Intanza 9mcg® - ***Summary of Product Characteristics*** (SPC), 18/02/13 (accessed from Electronic Medicines Compendium on 22/08/13).
- Sanofi Pasteur MSD Ltd., Intanza 15mcg® - ***Summary of Product Characteristics*** (SPC), 18/02/13 (accessed from Electronic Medicines Compendium on 22/08/13)
- NHS England, November 2013: Public health functions to be exercised by NHS England - Service specification No.13 - Seasonal Influenza immunisation programme.

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

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 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.

Individual Healthcare Professional Authorisation

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

- **This page is to be retained by the individual healthcare professional/practitioner.**
- Each healthcare professional should have access to their own signed copy of the full PGD.
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- 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).
- 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:-_____

I have read and understood the Patient Group Direction.

INFLUENZA VACCINE (Seasonal Flu Vaccine)

I agree to administer Influenza (Seasonal Flu) vaccines only in accordance with this Patient Group Direction (NECSAT 2014/011)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

I agree that the above named healthcare professional is authorised to administer medicines in accordance with this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

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

Management & Monitoring of Patient Group Direction NECSAT 2014/011

INFLENZA (Seasonal Flu) VACCINES

Healthcare Professional Authorisation (service/practice list)

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

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

Influenza (Seasonal Flu) vaccines under the Patient Group Direction (NECSAT 2014/011)

PGD Valid from date: 1st September 2014 **PGD Expiry Date:** 31st August 2016

Healthcare Professional			**Authorised by:**		
Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

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