Patient Group Direction (PGD) for the Administration of

INFLUENZA (Seasonal Flu) Vaccines

by Registered Professionals to Individuals Accessing NHS Services in
Durham, Darlington, Tees, North Cumbria, Northumberland and 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 2018/015**

Valid from: 1st September 2018

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Expiry date: 30th September 2020

This patient group direction has been developed & produced by: -			
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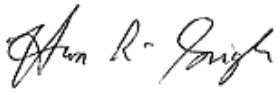
Medicines Optimisation Pharmacist (Lead Author) (North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		16/08/2018
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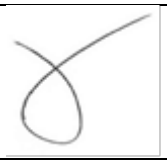
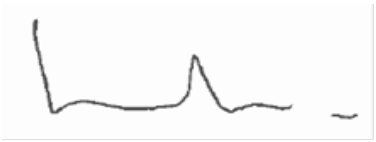
Assistant Medical Director (NHS England, Cumbria and North East)	**Dr James Gossow** *(Senior Doctor)*		24/08/2018

This PGD has been approved for use in Cumbria and North East Sub Region (NHS England) by:			
Title	Name	Signature	Date
Assistant Medical Director (NHS England Cumbria and North East)	**Dr Jonathan Slade** *(Governance Authorisation)*		25/08/2018

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)

Only use those criteria that are specific to your authorised role & competence. Ensure appropriate consent has been obtained/best interest decision is in place 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 26/03/18. PHE Gateway reference 2017863, Appendix A to E.

- **All those aged 65 years and over** (including 64 year olds becoming age 65 years by 31st March 2019)
- **All those from 6 months to less than 65 years of age with a serious medical condition** such as: -
  a) Chronic (long term) 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). Children who have previously been admitted to hospital for lower respiratory tract disease. (See precautions on live attenuated vaccines).
  b) Chronic heart disease - This includes congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
  c) Chronic kidney disease (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, e.g. Parkinson's disease or motor neurone disease; all patients with a learning disability; Stroke & TIA. Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers). Clinicians should also offer immunisation, based on individual assessment, to clinically vulnerable individuals including those with cerebral palsy, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability.
  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 on live attenuated vaccines), including those undergoing *chemotherapy leading to immunosuppression HIV infection at all stages,* bone marrow transplant, multiple myeloma or genetic disorders affecting the immune system (e.g. (e.g. IRAK-4, NEMO, complement disorder); 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 20kg, a dose of 1mg or more per kg per day.. Household contacts of immunocompromised individuals may be considered, i.e. those who expect to share living accommodation on most days over the winter. This may include carers. (It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician).
     Some immunocompromised patients may have a suboptimal immunological response to the vaccine.
  h) Asplenia or splenic dysfunction. Also includes conditions that may lead to splenic dysfunction e.g. homozygous sickle cell disease, coeliac disease.
  i) Morbidly obese (class III obesity) defined as BMI of 40kg/m^2 and above

Inclusion criteria - continued

- All children aged 2 and 3 years (but not 4yrs or older on 31/08/18) (i.e. DOB on or after 01/09/14 and on or before 31/08/16). (For delivery in GP Practices).
- All children in reception class and school years 1, 2, 3, 4 and 5 (i.e. aged 4 to 9 year olds, but not 10 years or older on 31 August 2018 - DOB on or after 01/09/08 and on or before 31/08/14) through locally commissioned arrangements.
- Primary school-aged children (from reception class through to year 6) in former primary school pilot areas through locally commissioned arrangements. At risk children who were eligible for school based programme may be offered vaccination if the school session is late in the season, the parents prefer it, or the child was absent on the day vaccination was offered in school.
- All pregnant women at any stage of pregnancy (1st, 2nd, or 3rd trimesters), including those that become pregnant during the flu season). (See precautions on live attenuated vaccines).
- 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 & cause high morbidity/mortality (it 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. Vaccination should be given on an individual basis at the GP's discretion in the context of other clinical risk groups in their practice.
- Household contacts of immunocompromised individual's i.e. individuals who expect to share living accommodation on most days of the winter and therefore for whom continuing close contact is unavoidable.
- 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. Influenza vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above.
- Health and social care staff, employed by a registered residential care/nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable patients/clients who are at increased risk from exposure to influenza
- Health and care staff, employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable patients/clients who are at increased risk from exposure to influenza
- Health and social care workers with direct patient/service user contact. Individuals not covered by the criteria above, should be vaccinated as part of an employer's occupational health obligation (see Chapter 12 of "The Green Book"). (NB. This PGD may be used by NHS organisation's occupational health providers to vaccinate these individuals but does not extend to the immunisation of individuals other than those with direct patient/service user contact, as recommended for influenza vaccination by JCVI and detailed in Chapter 12.
- Others involved directly in delivering health and social care such that they & vulnerable patients/clients are at increased risk of exposure to influenza.
- Locum GPs. To be vaccinated by the GP practice where they are registered as a patient (all other GP's and primary care staff are the responsibility of their employer as part of occupational health arrangements).

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

General exclusions

- No valid consent or best interest decision in place;
- Under 6 months of age;
- In general practice, healthy children that turn 2 years old after 31/08/2018
- 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).

Exclusion criteria - continued

- Confirmed anaphylactic reaction to a previous dose of the influenza vaccine.
- Confirmed anaphylactic reaction to any component, ingredient, or excipient of the vaccine (other than ovalbumin). See precautions.
- Confirmed severe anaphylaxis to egg which has previously required intensive care (refer to specialist for immunisation in hospital). Please also refer to precautions section - egg allergy.
- Hypersensitivity to formaldehyde & chicken protein or any excipient or residue listed within the vaccine's SPC or product information. (See also Precautions section).
- Are aged 2 years to under 18 years for whom live attenuated influenza vaccine (LAIV) is NOT contraindicated (or not otherwise unsuitable e.g. due to religious acceptance of porcine gelatin content) and is available.
- Have received a dose of influenza vaccine for the current season, unless they are individuals aged 2 to less than 9 years in a clinical risk group category listed in Chapter 19 of the "The Green Book" who should, in the first season they are vaccinated against influenza, receive a second dose of an appropriate influenza vaccine at least 4 weeks after the first 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 Quadrivalent Influenza vaccine Tetra MYL (Influenza virus surface antigen (inactivated)) - children less than 18 years old
- For Quadrivalent Influvac sub-unit Tetra (Influenza virus surface antigen (inactivated)) - children less than 18 years old
- For Fluad® (Surface antigen, inactivated, Adjuvanted with MF59C.1. (Seqirus UK Ltd) - Those under 65 years old
- For Influenza Vaccine (Split Viron, inactivated (trivalent)). (Pfizer Ltd) - children aged under 5 years.

Exclusions for Fluenz Tetra (Live Attenuated Influenza Vaccine – (LAIV))

- Children less than 24 months old. ● Children 18 years old and over. ● Pregnancy & breast feeding.
- Children aged 10 to 17 years old who are NOT in a clinical risk group category listed in Chapter 19 – Influenza (The Green Book) or who were not in a former primary school pilot programme for primary school aged children.
- Children in clinical risk groups under 18yrs of age who are medically contraindicated to LAIV (offer a suitable quadrivalent inactivated flu vaccine instead).
- Children & adolescents receiving salicylate therapy (other than for topical treatment of localised conditions)
- 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; and high dose corticosteroids (prednisolone at least 2mg/kg/day for 1 week or 1mg/kg/day for a month or equivalent).

  (NB. It is not contraindicated for use in children or adolescents with asymptomatic/stable 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).
- Those with a history of severe anaphylaxis to egg, which has previously required intensive care and those with clinical risk factors that contraindicate Fluenz Tetra®
- Children and adolescents with severe asthma or active wheezing, e.g. those who are currently taking oral steroids or who have been prescribed oral steroids in the last 14 days for respiratory disease. Children currently taking a high dose of inhaled corticosteroid (Budesonide >800mcgs/day or equivalent (e.g. Fluticasone >500mcgs/day), should only be given LAIV on advice from their specialist – as these children are a defined risk group for influenza, those who cannot receive LAIV should receive an inactivated influenza vaccine.
- In children with a history of active wheezing in the past 72hours or those who have increased their use of bronchodilators in the previous 72hrs at the time of vaccination. Vaccination with Fluenz Tetra® should be deferred for 72hrs. If their condition has not improved after a further 72hrs, these children should be offered an inactivated influenza vaccine.
- 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

- 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"
- Those children with clinical risk factors that contraindicate Fluenz Tetra® should be offered an inactivated injectable influenza flu vaccine - with very low ovalbumin content (less than 0.12mcg/ml). Refer to Section 2 (Table 1) for products with low ovalbumin content.
- Children currently taking a high dose of inhaled corticosteroid (Budesonide >800mcgs/day or equivalent e.g. Fluticasone >500mcgs/day), should only be given LAIV on the advice of their specialist. Those who cannot receive LAIV should receive an inactivated influenza vaccine.
- Vaccination with Fluenz Tetra® should be deferred in children with a history of active wheezing in the past 72hrs, or those who have increased their use of bronchodilators in the previous 72hrs. If their condition has not improved after a further 72hrs, then to avoid delaying protection, these children should be offered an inactivated influenza vaccine.
- There is a theoretical potential for transmission of live attenuated influenza virus in FLUENZ TETRA to immunocompromised contacts for one to two weeks following vaccination. Where close contact with very severely immunocompromised patients (e.g. bone marrow transplant recipients requiring isolation) is likely or unavoidable (for example, household members), however, appropriate alternative influenza vaccines should be considered. Please also refer to exclusion criteria for Fluenz Tetra.
- Very severely immunosuppressed individuals should not administer live attenuated influenza vaccine. Other healthcare workers who have less severe immunosuppression or are pregnant, should follow normal clinical practice to avoid inhaling the vaccine and ensure that they themselves are appropriately vaccinated
- Patients with egg allergy
  - Adults and children with a history of severe anaphylaxis to egg, which has previously required intensive care, should be referred to specialists for immunisation in hospital. LAIV is not otherwise contraindicated in children with egg allergy.
  - Adult patients, except those with severe anaphylaxis to egg, can also be immunised in any setting using an inactivated influenza vaccine with an ovalbumin content of less than 0.12mcg/ml (equivalent to 0.06mcg per 0.5ml dose). Refer to Section 2 (Table 1) for products with low ovalbumin content.
  - The JCVI have advised that, except for those with severe anaphylaxis to egg, which has previously required intensive care, children with an egg allergy can be safely vaccinated with Fluenz Tetra® [Live Attenuated Influenza vaccine (LAIV)] in any setting (including primary care & schools). LAIV (Fluenz Tetra®) has an upper ovalbumin limit of 0.12mcg/ml).
  - Those children who have both egg allergy and a clinical risk factor that contraindicates LAIV (e.g. immunosuppression) should be offered an inactivated injectable flu vaccine with a very low ovalbumin content (less than 0.12mcg/ml).
  - Egg-allergic children with asthma can receive LAIV if their asthma is well-controlled

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 severe anaphylaxis to egg, which has previously required intensive care, refer to specialist.

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 severe 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 in a Pre-filled Syringe (PFS); i.e.

- Inactivated quadrivalent influenza vaccine (QIV)
  (This includes LIVE Attenuated Influenza Vaccine (LAIV) as a 0.2ml / dose Nasal Spray (FLUENZ® Tetra ▼)
- Inactivated adjuvanted trivalent vaccine (aTIV)

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

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

Supplier	Name of product	Vaccine Type	Age indications	Ovalbumin content (µg/ dose)
AstraZeneca UK Ltd	FLUENZ® Tetra ▼ (nasal spray)	Live attenuated, nasal (quadrivalent) (Nasal spray suspension)	From 24 months to less than 18 years of age	≤ 0.12mcg/ml (≤ 0.024mcg / 0.2ml dose)
GlaxoSmithKline	Fluarix ™ Tetra ▼	Split virion inactivated virus (quadrivalent)	From 6 months	≤0.1mcg/ml ≤ 0.05mcg / 0.5ml dose
MASTA	Quadrivalent Influenza Vaccine (Split Virion, inactivated) ▼	Split virion inactivated virus	From 6 months	≤0.1mcg/ml ≤ 0.05mcg / 0.5ml dose
Mylan, (BGP Products)	*Imuvac® *Influvac ® sub-unit *Influenza vaccine MYL	Surface antigen, inactivated virus (trivalent)	From 6 months	0.2mcg/ml 0.1mcg / 0.5ml dose
	Quadrivalent Influenza vaccine Tetra MYL ▼	Influenza virus surface antigen (inactivated)	From 18 years	0.2mcg/ml 0.1/0.5ml dose
	Quadrivalent Influvac ® sub-unit Tetra ▼			
Pfizer Vaccines	*Influenza vaccine (split virion, inactivated), PFS	Split virion, inactivated virus, (trivalent)	From 5 years	≤ 2mcg/ml (≤1mcg / 0.5ml dose
Sanofi Pasteur	Quadrivalent Influenza Vaccine (split virion, inactivated) ▼	Split virion inactivated virus	From 6 months	≤0.1mcg/ml ≤ 0.05mcg / 0.5ml dose
Seqirus UK Ltd. (ACSL company)	Fluad®	Surface antigen, inactivated, Adjuvanted with MF59C.1 (adjuvanted Trivalent - aTIV)	65 years of age and over	≤ 0.4mcg/ml ≤ 0.2mcg / 0.5ml dose

▼ Black Triangle Drug (under intensive surveillance). * These are non-adjuvanted trivalent vaccines and are not one of the recommended vaccines for 2018/19. (Please also refer to the relevant SPCs & Green Book Chapter 19 - Influenza). None of the influenza vaccines for 2018/19 season contain thiomersal as an added preservative.

Legal Status:

POM –Prescription Only Medicine

- Adjuvanted trivalent inactivated flu vaccine (aTIV) - This is licensed for people aged 65 years and over.
  - Although it is stated in the SPC that Fluad® (aTIV) is indicated for patients aged 65 years and over, patients who will become 65 years of age by 31st March 2019 but who are 64 years at the time of vaccination can receive aTIV off-label in accordance with the recommendations for the national influenza immunisation programme for 2018/19

Dosage / Dose range:

NHS England and PHE Recommendations:

- 65 year olds and over (including 64 year olds turning 65 years by 31st March 19) receive an aTIV.
- Those under 65s in at risk groups, including pregnant women, receive quadrivalent influenza vaccines (QIV).
- QIV should also be offered to healthcare workers (HCW) aged under 65yrs. HCW aged 65yrs and over should be offered aTIV.
- Children aged from 2 years to less than 18 years are recommended to have a LAIV unless contra-indicated.
- 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 Figure 1 below for child eligibility and Special Considerations/Additional Information section).
NB. It is important that preterm infants who have risk factors have their immunisations at the appropriate chronological age. Influenza immunisation should be considered after the child has reached six months of age.

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

- Offer 1 dose of a suitable quadrivalent inactivated vaccine (QIV)
  (Those not previously vaccinated, a 2nd dose is recommended 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 LAIV (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. (If Fluenz Tetra is unavailable for this 2nd dose (due to batch expiry), a suitable inactivated injectable influenza vaccine can be given.
- If Fluenz Tetra® is medically contra-indicated (or is otherwise unsuitable, e.g. due to religious acceptance of porcine gelatin content), offer a suitable inactivated (split virion) QIV supplied centrally from ImmForm.

18 to 64 years old IN clinical risk groups, including pregnant women

- Offer 1 dose of a suitable QIV.

65 years old and over (including 64 year olds turning 65 years by 31 March 2019)

- Offer 1 dose of adjuvanted trivalent inactivated vaccine (aTIV) (Fluad®: Seqirus).
- The use of the aTIV (Fluad®) should be a priority for those aged 75 years and over, given that the non-adjuvanted vaccine has shown no significant effectiveness in this group over recent seasons.
- QIV should be offered as a second line option to aTIV (Fluad®) if aTIV (Fluad®) is unobtainable (see Special considerations/Additional Information) or otherwise unsuitable (e.g. due to egg allergy).

NB. Non-adjuvanted trivalent influenza vaccine (TIV) is not one of the recommended vaccines for 2018/19 but may be administered where the recommended vaccine choices as detailed above are unobtainable (see Additional Information).

Figure 1 – Child eligibility for flu vaccine & type to offer (from national flu immunisation letter 18/19: Page16)

Age on 31st August 2018	**Is child eligible for LAIV?**	**Setting** (in which it is normally offered)
Six months to less than two years old	**Universal programme:** - No. (Only at risk children are offered vaccination) **At risk children:** Offer suitable quadrivalent inactivated flu vaccine (QIV) (LAIV is not licensed for children under 2 year of age)	General Practice
Two to three year olds [Born between 1st September 2014 and 31st August 2016]	**Universal programme:** - All 2 and 3 year olds offered LAIV. - Children who turn 2 years of age after 31st August 2018 are not eligible - Children who were 3 on 31st August 2018 & turn 4 afterwards, are still eligible **At risk children:** - Offer LAIV (Fluenz Tetra). - If child is medically contra-indicated (or it is otherwise unsuitable), then offer suitable quadrivalent inactivated flu vaccine (QIV)	General Practice
Aged 4 to 9 years old [Born between 01/09/2008 and 31/08/2014]	**Universal programme:** - All primary school years from reception class to year 5* offered LAIV. **At risk children:** - Offer LAIV (Fluenz Tetra). - If child is medically contra-indicated (or it is otherwise unsuitable), then offer suitable inactivated flu vaccine. - At risk children may be offered vaccination in general practice if the school session is late in the season, parents prefer it, or they have missed the school session. Also, some schools may not offer inactivated vaccines to at risk children in whom LAIV is contraindicated.	School based provision
Aged 10 years old to less than 18 years	**Universal programme:** - No. (Only at risk children are offered vaccination) **At risk children:** - Offer LAIV (Fluenz Tetra). - If child is medically contra-indicated (or it is otherwise unsuitable), then offer suitable quadrivalent inactivated flu vaccine (QIV)	General Practice

*(Reception class (is 4 to 5 year olds); Year 1 (5 to 6 year olds); Year 2 (6 to 7 year olds); Year 3 (7 to 8 year olds); Year 4 (8 to 9 year olds); Year 5 (9 to 10 year olds).

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).
- Due to the presence of adjuvant (MF59C), Fluad® should be administered intramuscularly using a 25mm needle.
- Fluenz® Tetra (-(LAIV) 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.
- Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy.

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

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: **0.2ml** (Nasal)
0.5ml (all inactivated vaccines)

Maximum number of vaccinations: **Two doses**

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

- However, children aged 6 months to under 9 years of age who are in clinical risk groups and have not received influenza vaccine previously, should receive 2 doses 4-6 weeks apart are given.
- For Children aged 2 years to under 9 years of age who are not in a clinical risk group, the JCVI have advised that only a single dose of LAIV is required irrespective of whether they have received influenza vaccine previously. (NB. This advice differs from that in the SPC for Fluenz® Tetra). This differs for Influenza vaccine (split virion, inactivated) by Pfizer Ltd.

  - For Influenza vaccine (split virion, inactivated), prefilled syringe (Pfizer Ltd): this applies to children aged 5 to 9 year olds

NB. The inactivated influenza vaccines are interchangeable, although the individual's age and vaccine licence should be considered. (Please see Dosage/Dose range section above and refer to individual manufacturer's SPC for additional details).
(Please also refer to Green Book Chapter 19 – Influenza for additional information).

Follow up treatment:

As above. See also current PHE Green Book recommendations, Chapter 19, pages 10-11.

https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19

3. Further Aspects of Treatment:

Relevant Warnings & Potential Adverse Effects

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

- A higher incidence of mild post-immunisation reactions has been reported with Fluad compared to non-adjuvanted influenza vaccines

Potential Adverse Effects/Reactions: -

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

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

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 Following Immunisation (AEFI)

- Report to doctor if appropriate & document in patient's medical records.
- All suspected AEFIs 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 (October 2015)

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.
- LAIV contains a highly processed form of gelatine (derived from pigs). Some faith groups do not accept the use of porcine gelatine in medical products. Current policy is that only those who are in clinical risk groups and/or have a medical contra-indication to LAIV are able to receive an inactivated injectable vaccine as an alternative.
- If the child sneezes, blows their nose or has nasal dripping following administration of LAIV, the vaccine dose does not need to be repeated.
- 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.
- LAIV (Fluenz® Tetra) is the influenza vaccine of choice in all 2 to 17 year olds unless it is unsuitable.
- Other live attenuated vaccines, such as MMR, administered as part of the routine childhood immunisation programme can be given at the same time or at any interval before or after Fluenz® Tetra.
- Flu antiviral agents and LAIV (Fluenz® Tetra) should not be administered concurrently. Administration of flu antiviral agents are likely to reduce the effectiveness of Fluenz® Tetra if given within 48 hours before administration or within two weeks of administration.
- 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.
- Generic influenza vaccine (Split Virion, inactivated) [Pfizer 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.
- Patients with a learning disability: PHE understand the difficulty with vaccinating this group with injectable vaccines. PHE advises that LAIV is not licensed for adults so practice should attempt to vaccinate using an injectable vaccine. Previously, it has been found that LAIV is easier to use in similar patients and is less distressing. However, in the event that an injectable vaccine is not appropriate, GP's can use their clinical discretion to use the LAIV vaccine off license.
- The recommended vaccine in those aged 65 years and over is aTIV QIV should not be offered to those aged 65 years and over, other than in exceptional circumstances. In the event that aTIV is not available, and is highly unlikely to become available, QIV may be offered as a second line option. Before offering the second line option, however, individuals should be sign-posted to other providers to access the recommended vaccine, as appropriate.
- Non-adjuvanted trivalent influenza vaccine (TIV) is not one of the recommended vaccines for 2018/19. For those aged under 65 years, if QIV is not available, and is highly unlikely to become available, TIV may be offered as a second line option. For those aged 65 years and over, if neither QIV nor aTIV are available, and are highly unlikely to become available, TIV may be administered in exceptional circumstances. In both situations, individuals should be sign-posted to other providers to access the recommended vaccine, as appropriate.
- If offering QIV to individuals not recommended to have it, or if offering non-adjuvanted TIV to any individual, when gaining consent for immunisation, practitioners should ensure they inform the individual the vaccine is not one nationally recommended for them. Healthcare practitioners should ensure they explain to the individual the possible lower efficacy of the vaccine being offered to them, why it is being offered instead of the recommended vaccine and why it may still offer protection against seasonal flu, or attenuate the progression of the infection should they get it. The discussion should be documented in the individuals' records.

(Please see relevant online Green book chapter, Tripartite Letter - PHE Gateway Ref:2017863 and the manufacturer's SPCs

References

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- Seqirus Vaccines Ltd, Fluad® - *Summary of Product Characteristics*, 17/05/18 (accessed from EMC on 16/08/18).
- Sanofi Pasteur, Quadrivalent Influenza Vaccine (split virion, inactivated) ▼ , suspension for injection in prefilled syringe - *Summary of Product Characteristics*, 10/01/2018 (accessed from EMC on 16/08/2018).
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- *Public Health England & Royal College of Nursing*: National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners (February, 2018). Accessed at https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners on 16/08/2018.
- *NHS England*: Enhanced Service Specification – Childhood seasonal influenza vaccination programme 2018/19 (July 2018)
- *NHS England*: Direct Enhanced Service Specification – Seasonal influenza and pneumococcal polysaccharide vaccination programme 2018/19 (June 2018).

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 National minimum standards & competencies in immunisation training as defined in the PHE & RCN publication, "National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners (February 2018)," 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 2018/015)

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 2018	Review Date: - June 2020	**Expiry Date: - 30th September 2020**

Management & Monitoring of Patient Group Direction NECSAT 2018/2015

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 2018/015)

PGD Valid from date: 1st September 2018 **PGD Expiry Date:** 30th September 2020

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

PGD Valid from: 1st Sept 2018	Review Date: - June 2020	**Expiry Date: - 30th September 2020**