Public Health England

NHS England

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Amendment Dates:	**Page(s)**	**Brief Description**

Patient Group Direction for administration of Fluenz Tetra® ▼nasal spray suspension (influenza vaccine, live) during flu immunisation programme 2014/15

Approved By

NHS England Shropshire and Staffordshire Area Team	Name	Signature
Medical Director	**Dr Ken Deacon**	
LPN Pharmacy Chair	**Dr Manir Hussain**	
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Date of patient group direction approved	September 2014
Date this patient group direction becomes due for review	August 2015 or in response to new local/national guidelines.

STAFF CHARACTERISTICS

- Provider of NHS services within NHS England (Shropshire & Staffordshire Area Team)
- Registered nurse with current NMC registration

Specialist competencies or qualifications:

- The health care professional should undertake the Public Health England training for healthcare practitioners on the national childhood flu immunisation programme 2014/15[1] which can be accessed via (https://www.gov.uk/government/publications/childhood-flu-programme-training-slide-set-for-healthcare-professionals).
- The health care professional must have a good understanding of the NICE Good Practice Guidance on Patient Group Directions[2].
- The NICE competency framework: For health professionals using Patient Group Directions[3] should be used by health care professionals planning to work under this PGD to identify any gaps in their knowledge. The gaps should be addressed before the healthcare professional is authorised to work under this PGD.
- The clinical manager/ lead GP must have evidence that the health care professional has undertaken training to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.
- The healthcare professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.
- The clinical manager/ lead GP must have assessed the competency of the healthcare professional to work to this Patient Group Direction. The NICE competency framework: For health professionals using Patient Group Directions[3] should be used to support this assessment.
- The health care professional must have undertaken training and annual updates in the recognition and treatment of anaphylaxis, including practical in Basic Life Support and has immediate access to an in-date supply of adrenaline 1mg in 1ml (1:1000) at the time of the consultation. (The practitioner must be deemed competent in basic life support and in emergency administration of adrenaline)
- The health care professional must have access to all relevant sources of information e.g. information issued by the Department of Health (Green Book), British National Formulary (BNF), Summary of Product Characteristics (SPC), and the clinical guideline concerning medicine(s) within this Patient Group Direction (PGD).
- The practitioner must be competent and knowledgeable in vaccine cold chain standards.
- The registered health care practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession's Code of Professional Conduct and Ethics.

YOU MUST BE AUTHORISED BY NAME BY YOUR CLINICAL LEAD UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

CLINICAL CONDITION	
Clinical need addressed	• In accordance with The national flu immunisation programme 2014/15[4] **Fluenz Tetra®** is indicated for the active immunisation of:- ○ Children aged 2, 3 and 4 years, including children in this age group in risk groups (see inclusion criteria). ○ Children aged 5 to less than 18 years in risk groups (see inclusion criteria). for the prevention of influenza infection
Inclusion criteria	• Individuals meeting criteria for influenza immunisation with Fluenz Tetra® vaccination under the current vaccination programme: **All children aged two, three and four years old (but not five years or older) on 1 September 2014 (i.e. children whose date of birth is on or after 2nd September 2009 and on or before 1st September 2012) (including those in the clinical risk groups listed below)[4,5].** **Children aged 5 to less than 18 years old who are in a clinical risk group listed below[4,5]** (NB: Secondary school aged children in Years 7 and 8, in Shropshire/Telford & Wrekin and Staffordshire / Stoke on Trent, will be offered flu vaccination as part of a regional pilot. These children will be vaccinated through a schools based programme and fall outside this PGD unless the child is in one of the clinical risk groups listed below)

Eligible Group[4,5]	Further Details
Chronic respiratory disease aged six months or older∞	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 and 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.
Chronic heart disease aged six months or older∞	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
Chronic kidney disease aged six months or older∞	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease aged six months or older∞	Cirrhosis, biliary atresia, chronic hepatitis
Chronic neurological disease aged six months or older∞	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers).

		Clinicians should consider on an individual basis the clinical needs of patients including individuals with cerebral palsy, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological or severe learning disability.
	Diabetes aged six months or older∞	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic medicines, diet controlled diabetes.
	Immunosuppression aged six months or older∞ **(NB see exclusion criteria below for this risk group)**	Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, compliment deficiency). Individuals treated with or likely to be treated with systemic steroids for more than a month 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. 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.
	Asplenia or dysfunction of the spleen	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
	People living in long-stay residential care homes or other long-stay care facilities	Vaccination is recommended for 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.
	Carers	Those who are in receipt of a carer's allowance, or those who are the main carer, or the carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill. **Vaccination should be given on an individual basis at the discretion of the practitioner.** (Please note – this category refers to individual carers entitled to a free flu vaccine on the NHS, not

	professional health and social care workers who should be vaccinated by their employer, as part of an occupational health programme).

Selecting the appropriate vaccine for children

Fluenz Tetra® is the vaccine of choice in these groups because it is more effective in children than other inactivated influenza vaccines[4,5].

Eligible cohort	Vaccine to be offered
Six months to less than 2 years old in clinical risk group[4,5]	Offer suitable inactivated flu vaccine – Refer to Inactivated Influenza PGD
Children aged two, three or four years who are not in a clinical risk group[6]	Offer live attenuated influenza vaccine (Fluenz Tetra®) – using this PGD. If Fluenz Tetra® is contraindicated or not recommended, offer a suitable inactivated flu vaccine using the Inactivated Influenza PGD *.
Two years old to less than 18 years old in clinical risk[4,5]	Offer live attenuated influenza vaccine (Fluenz Tetra®) – using this PGD. If Fluenz Tetra® is contraindicated or not recommended, offer a suitable inactivated flu vaccine using the Inactivated Influenza PGD *
Child contacts of very severely immunocompromised individuals[7]	Offer suitable inactivated flu vaccine using the Inactivated Influenza PGD

* Refer to the PGD for inactivated influenza vaccine.

BEWARE OF PRODUCT CONFUSION!
Care must be taken not to confuse the two 'Tetra' brands. One way of remembering which vaccine is which is[1]:-

- Fluenz is the nasal flu vaccine (covered by this PGD)
- Fluarix is the arm injected vaccine (refer to PGD for inactivated influenza vaccine)

Exclusion criteria

(for full details of interacting medicines refer to current Summary of Product Characteristics (SPC) www.medicines.org.uk & BNF)

Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Children who do not meet the inclusion criteria defined above i.e.

- **Children under 2 years of age on 1st September 2014 (i.e. children born after 1st September 2012)[4,5]**
- **Children aged 5 to less than 18 years of age who are not in one of the risk group categories defined above[4,5]**
- **Adults (i.e. anyone aged 18 years and older)[4,5]**

In addition Fluenz Tetra® should NOT be given to:

- Individuals with a confirmed anaphylactic reaction to a previous dose of influenza vaccine or to any components of the vaccine[5]
- Hypersensitivity to the active substances or to any of the excipients of the vaccine (e.g. gelatin) including gentamicin (a possible trace residue)[8]
- Hypersensitivity to eggs or to egg proteins (e.g. ovalbumin) (see section below - management of excluded patients)[5]

- Individuals receiving salicylate therapy. This is because of the association of Reye's syndrome with salicylates and wild-type influenza infection[5,8]
- Currently taking or has been prescribed oral steroids in the last 14 days[1,5]. (see below under immunosuppressed individuals)
- Currently taking a high dose inhaled steroid – Budesonide >800micrograms/day or equivalent (e.g. Fluticasone >500 micrograms/day) because of limited safety data in these groups[1,5].
- Pregnant females (see actions if excluded below) - Please note:
  There is no need, however, to specifically test eligible girls for pregnancy or to advise avoidance of pregnancy in those who have been recently vaccinated[1,5,8]
- Breast feeding females – although it is not known whether Fluenz Tetra® is excreted in human milk, as some viruses are, Fluenz Tetra® should not be administered to breast feeding mothers[8]
- **Immunosuppressed individuals[9]**

  Live vaccines can, in some situations, cause severe or fatal infections in immunosuppressed individuals due to extensive replication of the vaccine strain. For this reason vaccination should only be conducted in consultation with an appropriate specialist and therefore falls outside this PGD.

  The following individuals should not receive live vaccines:

  - patients with evidence of severe primary immunodeficiency, e.g. severe combined immunodeficiency, Wiskott-Aldrich syndrome and other combined immunodeficiency syndromes
  - patients currently being treated for malignant disease with immunosuppressive chemotherapy or radiotherapy, or who have terminated such treatment within at least the last six months
  - patients who have received a solid organ transplant and are currently on immunosuppressive treatment
  - patients who have received a bone marrow transplant, until at least 12 months after finishing all immunosuppressive treatment, or longer where the patient has developed graft-versus-host disease.
  - patients receiving systemic high-dose steroids, until at least three months after treatment has stopped. This would include children who receive prednisolone, orally or rectally, at a daily dose (or its equivalent) of 2mg/ kg/day for at least one week, or 1mg/kg/day for one month. Occasionally, individuals on lower doses of steroids may be immunosuppressed and at increased risk from infections.
  - patients receiving other types of immunosuppressive drugs (e.g. azathioprine, cyclosporin, methotrexate, cyclophosphamide, leflunomide and the newer cytokine inhibitors) alone or in combination with lower doses of steroids, until at least six months after terminating such treatment.
  - patients with immunosuppression due to human immunodeficiency virus (HIV) infection.

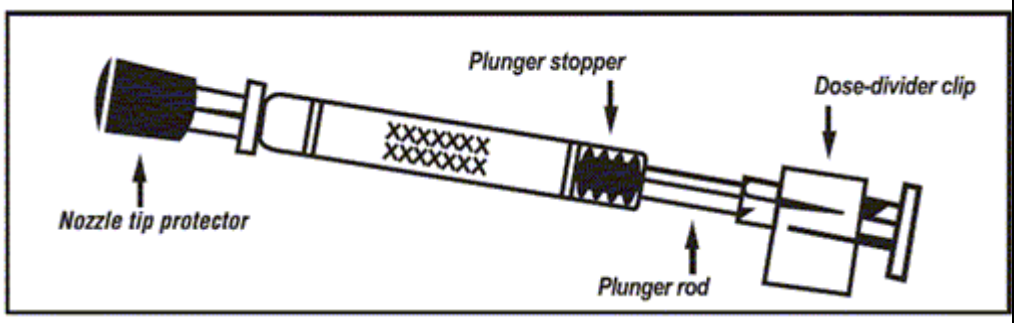
	Where a clinician believes that vaccination with Fluenz Tetra® is appropriate for an immunosuppressed individual, vaccination would fall outside the remit of this PGD and therefore a patient specific direction (PSD) should be provided by the clinician. **Temporary Exclusion** Infants and children suffering from heavy nasal congestion. This is because heavy congestion may impede delivery of the vaccine to the nasopharyngeal mucosa[5] Children with active wheezing at the time of vaccination or severe asthma (until at least 7 days after wheezing has stopped)[1,5] If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. NB: Minor illnesses without fever or systemic upset are NOT valid reasons to postpone immunisation[1]. **Non consenting individuals** Individuals, or those giving consent on their behalf, must be given enough information to enable them to make a decision before they can give consent. This should include information about the vaccine, its contents, the vaccination process, benefits and risks of the immunisation(s)
Caution/need for further advice	• Exclusion under this Patient Group Direction (PGD) does not necessarily mean the vaccination is contraindicated but it would be outside the remit of the PGD and another form of authorisation (PSD) may be required. • There is a potential for transmission of the live attenuated flu virus in Fluenz Tetra® to very severely immunosuppressed contacts (for example bone marrow transplant patients requiring isolation). This risk is for the period of one to two weeks following vaccination. Where close contact with very severely immunosuppressed contacts (for example household members) is likely or unavoidable, consideration should be given to using an appropriate inactivated flu vaccine[1] • No data exist regarding the safety of intranasal administration of Fluenz Tetra® in children with unrepaired craniofacial malformations[8]. • Fluenz Tetra® contains pork gelatin. Immunisers must ensure vaccine recipients or parents consenting for vaccination are informed about excipients of Fluenz Tetra® before administration. (For individuals who refuse Fluenz Tetra® because of pork gelatin content see management of excluded patients below). NB porcine gelatin has been certified as acceptable by multi-faith groups see https://www.gov.uk/government/news/vaccines-and-gelatine-phe-response
Management of excluded patients	• Document in the individual's notes, advise and counsel accordingly • Refer to medical practitioner or seek appropriate advice from a Consultant in Health Protection if necessary Where age is the exclusion criteria, no further action will be required. **Pregnancy** All pregnant females should be offered inactivated influenza vaccine (see inactivated influenza PGD)

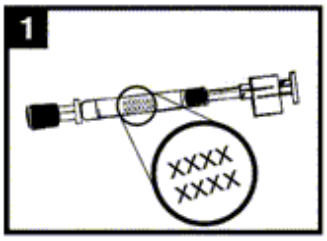
	Breastfeeding All breastfeeding females, in a risk group, should be offered inactivated influenza vaccine (see inactivated influenza PGD) **Immunosuppression** Vaccination with inactivated influenza vaccine should be considered in patients with immunosuppression who are eligible for influenza vaccination but excluded from immunisation under this PGD (see section on exclusion and inactivated influenza PGD). **Egg allergy** There is no licensed egg-free influenza vaccine available to vaccinate children under 18 years of age during 2014/15. Children with egg allergy should be immunised in primary care using an inactivated influenza vaccine with an ovalbumin content less than 0.12 µg/ml (equivalent to 0.06 µg for 0.5ml dose) - refer to PGD for inactivated influenza vaccine[1]. Only children who have either confirmed anaphylaxis to egg or egg allergy and severe uncontrolled asthma should be referred to specialists for immunisation in hospital[1]. **Temporary exclusion** In the case of postponement due to active wheezing, severe asthma, acute illness or heavy nasal congestion, arrange a future date for vaccination (if inclusion criteria still apply). **Children IN clinical risk groups for whom Fluenz Tetra® is unsuitable** For those children in clinical risk groups for whom Fluenz Tetra® is unsuitable (contraindicated or refused), a suitable inactivated influenza vaccine should be offered. (see inactivated influenza PGD) **Children aged two, three and four years old (but not five years or older) on 1 September 2014 (i.e. date of birth on or after 2nd September 2009 and on or before 1st September 2012) NOT IN clinical risk groups** For those children NOT in clinical risk groups for whom Fluenz Tetra® is contraindicated a suitable inactivated influenza vaccine should be offered. (see inactivated influenza PGD) Children who are **NOT** in a clinical risk group who do not have a contraindication to Fluenz Tetra® but refuse the Fluenz Tetra® vaccine should NOT be offered inactivated influenza vaccine[5].
Action for patients not wishing to receive care under this PGD	• Advise the individual about the protective effects of the vaccine, the risks of infection, including potential complications. • Document action and advice given • Refer to medical practitioner where appropriate - doctor or independent prescriber

Treatment and Drug details	
Name, form and strength of medicine	Fluenz Tetra® (influenza vaccine, live) nasal spray suspension (0.2 ml) in pre-filled nasal applicator. Fluenz Tetra® contains cold-adapted, temperature sensitive, attenuated virus strains[8].

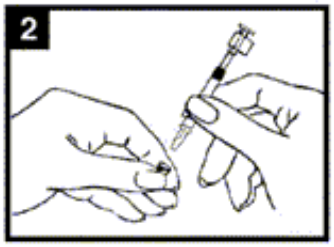
	Marketed by AstraZeneca UK Limited
Presentation	Fluenz Tetra® vaccine is supplied as a nasal spray suspension, colourless to pale yellow, clear to opalescent. Small white particles may be present. The suspension (0.2ml) is contained in a single-use nasal applicator with a plunger, plunger-stopper, dose-divider clip and protective tip cap[1,8]. The nasal applicator allows a divided dose of 0.1ml to be administered in both nostrils (total dose of 0.2ml, 0.1ml in each nostril)[1,8]
Legal classification	POM (Prescription only medicine)
Black triangle warning▼ Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme (www.yellowcard.gov.uk).	Yes - All suspected adverse reactions must be reported to the MHRA using Yellow Card reporting scheme.
Method of obtaining supply	Order through the ImmForm website (www.immform.dh.gov.uk) Public Health England (PHE) has centrally procured both live and inactivated flu vaccine for all children aged from 6 months to less than 18 years old[1]. This is for those children who are part of the extension of the programme (2, 3 and 4 years and pilots) **and** those children in clinical risk groups who are not part of the extension (i.e. PHE will supply Fluenz Tetra® for those who can receive it and inactivated flu vaccine for those children for whom Fluenz Tetra® is not suitable or contraindicated)[1]. If you require any further assistance in relation to the ordering process please call the ImmForm Helpdesk on 0844 376 0040
Site for treatment	GP surgeries
Route/method	**Fluenz Tetra® vaccine is given intranasally.** **Fluenz Tetra® vaccine must NOT be injected**. Instructions for administration of the vaccine: Single application in each nostril of 0.1ml **Check expiry dates before administration. Fluenz Tetra ® has an expiry date of 18 weeks after manufacture this is much shorter than inactivated influenza vaccine. It is highly likely that all the Fluenz Tetra® supplied centrally will have expired by February 2015. It is therefore important to ensure that efforts are made to vaccinate children before the Christmas holidays[1]** To administer the vaccine, carefully remove the rubber nozzle tip protector without removing the dose-divider clip at the other end of the applicator. With the patient in an upright position, place the tip just inside the nostril and depress the plunger as rapidly as possible. Pinch and remove the dose-divider clip from the plunger and repeat administration of the remaining vaccine into the other nostril immediately or as soon as possible. The patient can breathe normally during vaccine administration and there is no need to actively inhale or sniff.

Fluenz Tetra® Administration guide





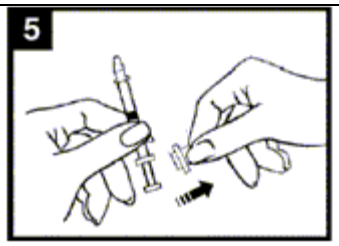
Check expiry date
Product must be used before date on applicator label.



Prepare the applicator
Remove rubber tip protector. **Do not remove** dose-divider clip at the other end of the applicator

Position the applicator
With the patient in an upright position, place the tip just inside the nostril to ensure FLUENZ Tetra ®is delivered into the nose.

Depress the plunger
With a single motion, depress plunger **as rapidly as possible** until the dose-divider clip prevents you from going further.



Remove dose-divider clip
For administration in the other nostril, pinch and remove the dose-divider clip from plunger

Spray in other nostril
Place the tip just inside **the other nostril** and with a single motion, depress plunger **as rapidly as possible** to deliver remaining vaccine.

Neither divided dose needs to be repeated if the patient sneezes, blows their nose or gets a runny nose immediately after the dose is administered. This is because the vaccine is absorbed very quickly and is still likely to be effective[ii].

The Summary of Product Characteristics for Fluenz Tetra® provides further guidance on administration.
http://www.medicines.org.uk/emc/medicine/25084

Administration by healthcare staff in clinical risk groups

In theory, healthcare workers may have low level exposure to live attenuated influenza vaccine viruses during administration of the vaccine and/or from recently vaccinated patients. The vaccine viruses are cold-adapted and attenuated, and are unlikely to cause symptomatic influenza. The risk of acquiring vaccine viruses from the environment is unknown but is probably low. As a precaution, however, 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[5,6].

Administration of Fluenz Tetra® with other vaccines

Fluenz Tetra® can be given at the same time as, or at any interval before or after other vaccines, including live vaccines. Although it was previously recommended that, where vaccines cannot be administered simultaneously, a four-week interval should be observed between live viral vaccines, JCVI have now advised that no specific intervals need to be observed between the live attenuated intranasal influenza vaccine and other live vaccines[5]

Fluenz Tetra® may reduce the effectiveness of the rubella component of the MMR vaccine but this is unlikely to be of clinical significance provided 2 doses of MMR have or will have been given[8]

Dose	**Immunisation Schedule** **Single dose of 0.2ml Fluenz Tetra® intranasal vaccine (administered as 0.1ml in each nostril) should be offered to:** • children aged 2, 3 and 4 years who are not in one of the risk group categories listed in the inclusion criteria • Children aged 9 to less than 18 years in a risk group category listed in the inclusion criteria **Two doses of 0.2ml Fluenz Tetra® intranasal vaccine, administered at least 4 weeks apart (each dose administered as 0.1ml in each nostril) should be offered to**: • children aged 2 to less than 9 years who are in a risk group category (see inclusion criteria) **AND** who have **not** received influenza vaccine before **See Appendix 1** - Chart summarising the advice on influenza vaccination for the 2014/15 influenza vaccination programme[7] The patient information leaflet provided with Fluenz Tetra® suggests children should be given two doses of this vaccine if they have not had flu vaccine before. However, JCVI considers that the public health benefit would be greater if the quantity of Fluenz Tetra® that is available is offered as a single dose to more children. This is because a second dose of the vaccine provides only modest additional protection[4,5]. On this basis, JCVI has advised that, when extending the flu immunisation programme to children, most children should be offered **a single dose** of the Fluenz Tetra®. However, children in risk groups aged two to less than nine years who have not received flu vaccine before should be offered two doses of Fluenz Tetra® (given at least four weeks apart)[4,5].
Number of times treatment may be administered	Most children should be offered **a single dose** of the Fluenz Tetra®. However, children in risk groups aged two to less than nine years who have not received flu vaccine before should be offered two doses of Fluenz Tetra® (given at least four weeks apart)[4,5].
Quantity to be supplied or administered	See **Dose** section above
Side effects *Suspected adverse reactions to drugs including vaccines should be reported on the yellow card available at the back of the BNF. Also at www.yellowcard.gov.uk*	Adverse reaction frequencies are reported as[8]: • Very common (≥ 1/10) • Common (≥ 1/100 to < 1/10) • Uncommon (≥ 1/1,000 to < 1/100) • Very rare (< 1/10,000) The most common adverse reaction observed in clinical studies was nasal congestion/rhinorrhoea.

	Adverse reactions	Frequency
Immune system disorders	Hypersensitivity reactions (including facial oedema, urticaria and very rare anaphylactic reactions)	Uncommon
Metabolism and nutrition disorders	Decreased appetite	Very common

Nervous system disorders	Headache	Very common
Respiratory, thoracic, and mediastinal disorders	Nasal congestion/rhinorrhoea Epistaxis	Very common Uncommon
Skin and subcutaneous tissue disorders	Rash	Uncommon
Musculoskeletal and connective tissue disorders	Myalgia	Common
General disorders and administration site conditions	Malaise Pyrexia	Very common Common

A detailed list of adverse reactions associated with Fluenz® is available in the Summary of Product Characteristics for this vaccine[iv], which is available from the European Medicines Agency website:
http://www.medicines.org.uk/emc/medicine/25084

Additional Information
(Includes advice about storage and disposal)

- Store in a refrigerator (2^0C – 8^0C)
- Do not freeze
- Protect from light
- Before use, the vaccine may be taken out of the refrigerator, without being replaced, for a maximum period of 12 hours at a temperature not above 25°C. If the vaccine has not been used after this 12-hour period, it should be disposed of[1,8].
- Equipment used for vaccination should be disposed of by placing in a proper, puncture-resistant 'sharps' box according to local authority regulations and guidance in Health Technical Memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)[6].

Fluenz Tetra® has an expiry date 18 weeks after manufacture – this is much shorter than inactivated influenza vaccines. Expiry dates should be checked regularly.

It is highly likely that all the Fluenz Tetra® supplied centrally will have expired by February 2015. It is therefore important to ensure that efforts are made to vaccinate children before the Christmas holidays[1]

Drug Interactions

There is a potential for flu antiviral agents to lower the effectiveness of Fluenz Tetra®. Therefore, influenza antiviral agents and Fluenz Tetra® should not be administered concomitantly. Fluenz Tetra® should be delayed for at least 48 hours after cessation of treatment with flu antiviral agents. Administration of flu antiviral agents within two weeks of administration of Fluenz Tetra® may adversely affect the effectiveness of the vaccine[1,5]

Fluenz Tetra® should not be administered to children receiving salicylate therapy (see exclusion criteria above). Salicylates should also be avoided for 4 weeks after vaccination unless medically indicated[5,8].

Administration of Fluenz Tetra ® with other vaccines – see section **route/method** above.

Advice to patient/carer

BEFORE TREATMENT:

- Supply marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine (as this recommends that two doses of the

	vaccine are administered, explain why a single dose is being offered to most children – refer to dosage section of PGD) • Advise parent/carer of possible common side effects and their management • The parent/carer should be advised to seek medical advice in the event of a severe adverse reaction. • Vaccine recipients or parents consenting for vaccination must be informed about excipients of Fluenz Tetra® before administration. (Fluenz Tetra® contains pork gelatin) (see page 8 'Caution/need for further advice) **AFTER TREATMENT:** • Any serious adverse reaction to the vaccine should be documented in the individual's medical records. • 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[5]
Follow up	When applicable, advise parent/carer when the subsequent dose is due, otherwise no routine follow up required.
Suspected Adverse reactions	Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations. As with all vaccines, healthcare professionals and parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Any serious adverse reaction to the vaccine should be documented in the patient's medical record. The child's GP should be informed about any adverse reaction
Error reporting	Any incidents or near miss issues must be reported via the organisation's internal reporting system
RECORD KEEPING	
Documentation needed /treatment records to be kept for audit purposes *A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.*	• Patient's name, address, date of birth and registered GP • Record of informed consent • Manufacturer, vaccine name, product name, batch number, expiry date • Dose administered • Date of administration • Route of administration • Advice given to patient (including advice given if vaccination is declined) • Details of staff who administered (sign and print name) • Details of any adverse drug reactions, and action taken including informing GP • Record supplied via Patient Group Direction (PGD) in patients clinical record All records should be clear, legible and contemporaneous. This information should be recorded as appropriate in: Patient's General Practitioner record or other patient record, depending on location **AND** the personal Child Health record (PCHR) – the Red Book. A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.

	Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death. Data must be stored in accordance with Caldicott guidance and the Data Protection Act. • Reconciliation – stock balances should be reconcilable with receipts, administration records and disposal.

Register of practitioners qualified to administer
Fluenz® Tetra ▼nasal spray suspension influenza vaccine (live, attenuated)
under this Patient Group Direction

Name of clinical manager / GP Lead	
Signature of clinical manager / GP Lead	Date:
A copy of this page should be retained by the authorising manager for 2 years for audit purposes	
Please state clinical area where this PGD is in use	

Healthcare professional individual declaration

I have read and understood the Patient Group Direction and agree to supply/ administer this medicine only in accordance with this PGD

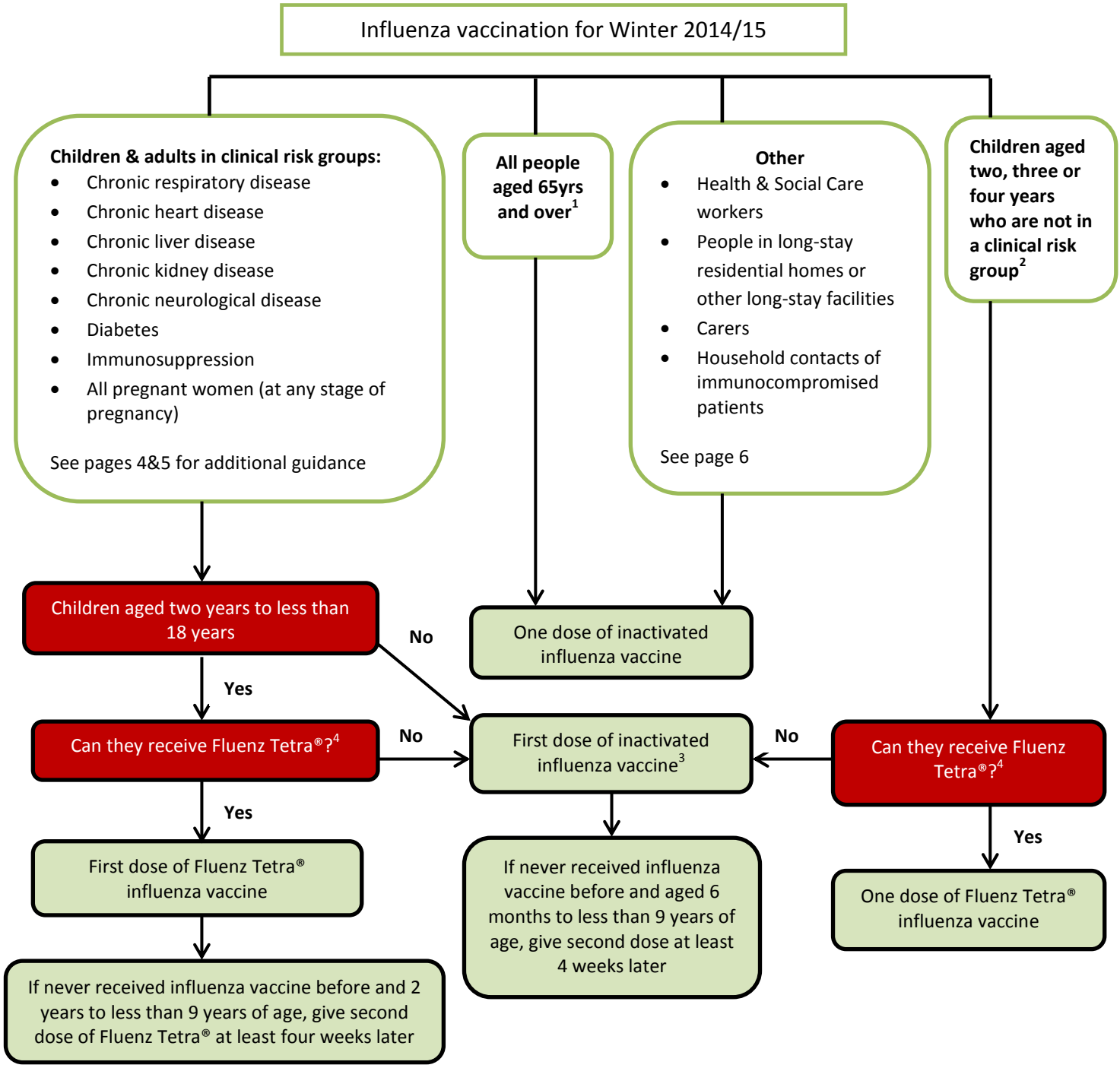
- **PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**.
- It is the responsibility of each professional to practice only within the bounds of their own competence.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

Name of professional (please print)	Signature	Authorising Manager (Must sign against each entry)	Date of authorisation

The clinical lead should review competency of authorised practitioners annually. Authorisation to use this PGD does not remove inherent professional responsibility and accountability

Appendix 1

Chart summarising the advice on influenza vaccination for the 2014/15 influenza vaccination programme[7].



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

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

3 if quadrivalent inactivated vaccine available, consider for **children age three years and older only**
If quadrivalent unavailable, offer suitable trivalent inactivated influenza vaccine. See page 7 which lists the vaccines that can be used in young children – **some are not suitable for young children.**

4 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.

References

[1] Public Health England. Training for healthcare practitioners. The national childhood flu immunisation programme 2014/15. Accessed via: https://www.gov.uk/government/publications/childhood-flu-programme-training-slide-set-for-healthcare-professionals
[2] National Institute for Health and Care Excellence. Good Practice Guidance: Patient Group Directions. August 2013
[3] National Institute for Health and Care Excellence. Competency framework: For health professionals using Patient Group Directions. January 2014
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[5] Public Health England. The national childhood flu immunisation programme 2014/15. Information for healthcare professionals. August 2014 Accessed via https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/340886/PHE__Childhood_influenza_programme_2014_15_.pdf
[6] The Green Book – Immunisation against infectious disease: Influenza Chapter 19
[7] Public Health England. Training for healthcare practitioners. The national immunisation programme 2014/15. Slide 17 accessed via:
[8] AstraZeneca. Fluenz nazal spray suspension influenza vaccine (live attenuated, nasal). Summary of Product Characteristics. Accessed via www.medicines.org 14 August 2014
[9] The Green Book – Immunisation against infectious disease: Contraindications and special considerations Chapter 6

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