Administration of Influenza Vaccines for 2015/16 season

Valid From: 1st August 2015

Lead Contact Mark Thomas, QE Gateshead: mark.thomas@ghnt.nhs.uk

Expiry Date: 1st August 2016

Review Date: 1st August 2016
1. Clinical Condition

<table>
<thead>
<tr>
<th>1.1</th>
<th>Define situation/condition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Administration of Influenza Vaccines for the 2015/16 influenza season</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>1.2</th>
<th>Criteria for inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patients that are over 2 years of age who require administration of prophylaxis of Influenza by vaccination.</td>
</tr>
</tbody>
</table>

Note: For children 2-11 years old, the inclusion applies only for experienced pharmacists who have given at least 20 vaccines in the past 12 months and have completed the Gateshead Health Clinical Skills Training Programme for Influenza Vaccines.

Note: It is the responsibility of the pharmacist to ensure the appropriate Influenza Vaccine product is used. All products must be used within the restriction of the product license and dosing recommendations.

<table>
<thead>
<tr>
<th>1.3</th>
<th>Criteria for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exclusions for Inactivated Influenza vaccines:</td>
<td></td>
</tr>
<tr>
<td>• Hypersensitivity to the active substances, to any of the excipients listed in the product SPC: <a href="http://www.medicines.org.uk/">www.medicines.org.uk</a> or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins) formaldehyde, cetyltrimethylammonium bromide, polysorbate 80, or gentamicin.</td>
<td></td>
</tr>
<tr>
<td>• Immunisation shall be postponed in patients with febrile illness or acute infection.</td>
<td></td>
</tr>
<tr>
<td>• Age restrictions are defined by the product license and are product specific. Please refer to product literature listed in the product SPC: <a href="http://www.medicines.org.uk/">www.medicines.org.uk</a></td>
<td></td>
</tr>
</tbody>
</table>

Exclusions for Fluenz Tetra (Live attenuated Influenza nasal vaccine): |
| • Children under 2 years of age |
| • Patients aged 18 years of age or over |
| • Children or adolescents with severe asthma or active wheezing: |
  | o Children with a history of active wheezing at the time of vaccination (until at least 7 days after wheezing has stopped) |
  | o Who are currently taking or have been prescribed oral steroids in the last 14 days |
  | o Who are currently taking a high dose inhaled steroid |
  | o In children and adolescents who meet step 5 of the BTS/ SIGN Clinical Guidelines on the management of asthma. |
| • Hypersensitivity to the active substances or to any of the excipients listed in the product SPC: [www.medicines.org.uk/emc/medicine/29112](http://www.medicines.org.uk/emc/medicine/29112) (e.g. gelatin), or to gentamicin (a possible trace residue), eggs or to egg proteins (e.g. ovalbumin). Note: There is no data on the use of Fluenz Tetra in children with egg allergy and the product should not be administered in this case. |
| • Children and adolescents with clinical immunodeficiency due to conditions or immunosuppressive therapy such as: acute and chronic leukaemias; lymphoma; symptomatic HIV infection; cellular immune deficiencies; and high-dose corticosteroids. Fluenz Tetra is not
contraindicated for use in individuals with asymptomatic HIV infection; or individuals who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or those receiving corticosteroids as replacement therapy, e.g. for adrenal insufficiency. Inactive vaccine should be considered.

- Children and adolescents younger than 18 years of age receiving salicylate therapy because of the association of Reye's syndrome with salicylates and wild-type influenza infection.

- Breastfeeding: It is not known if Fluenz Tetra is excreted in human milk, but as some live viruses can be excreted, mothers who are breastfeeding should be offered an inactivated vaccine.

- Pregnancy: There is no evidence of risk with Fluenz Tetra but because of the evidence of the safety of inactivated vaccine in pregnancy, pregnant patients should be offered the inactivated influenza vaccine. However, there is no need to specifically test for pregnancy, or to advise avoidance of pregnancy in those who have been recently vaccinated.

- Patients who are excluded because of severe asthma or active wheezing should be offered inactivated influenza vaccine

### 1.4 Cautions

**Cautions for Inactivated vaccine products:**

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

- Vaccine should under no circumstances be administered intravascularly.

- Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

- Interference with serological testing: Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false-positive reactions could be due to the IgM response by the vaccine.

**Cautions for Fluenz Tetra (Live attenuated Influenza nasal vaccine):**

- 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. Peak incidence of vaccine virus recovery occurred 2-3 days post-vaccination in Fluenz clinical studies. In circumstances where contact with severely immunocompromised individuals is unavoidable, the potential risk of transmission of the influenza vaccine virus should be weighed against the risk of acquiring and transmitting wild-type influenza virus.

- Fluenz Tetra should under no circumstances be injected.

- No data exist regarding the safety of intranasal administration of Fluenz Tetra in children with unrepaired craniofacial malformations.
1.5 Action if patient declines or excluded

- Influenza antiviral agents (e.g. Oseltamivir or Zanamivir) should not be administered within two weeks of administration of Fluenz Tetra, as they may adversely affect the effectiveness of the vaccine.

- Administration should be postponed in patients suffering from heavy nasal congestion until the congestion has resolved.

Refer patient to their medical practitioner for further review.

2. Characteristics of staff

2.1 Class of Health Professional for whom PGD is applicable

- Pharmacist registered with General Pharmaceutical Council.

2.2 Additional requirements considered relevant to the medicines used in the protocol

- The PGD can only be used by Pharmacists upon successful completion of the Gateshead Health Clinical Skills Training Programme for Influenza Vaccines, which includes:
  - CPR training course
  - Anaphylaxis training course
  - Influenza Vaccine administration training

2.3 Continued training requirements

- Up to date CPD record with General Pharmaceutical Council.

3. Description of Treatment

3.1 Generic Name of Medicine and Form e.g. tablets

- Influenza Vaccines for the 2015/16 influenza season as defined by the national NHS England Flu Plan.

See appendix 2 for Public Health England list of Vaccines or follow link below:


3.2 Legal status

- POM

3.3 Licensed or unlicensed

- Licensed

3.4 Dose(s) (Where a range is applicable include criteria for deciding on a dose)

- Inactivated Influenza Vaccines:

Dosing usually via pre-filled syringe but is age and product specific. It is the responsibility of the pharmacist working under this PGD to ensure the appropriate dose and correct administration, as defined by the product licence and SPC.

In adults the pre-filled dose is usually presented as a 0.5ml syringe, unless otherwise stated in the product literature.
**Fluenz Tetra (Live attenuated nasal vaccine):**

Fluenz Tetra nasal spray suspension (1 x 0.2ml) in a single-use nasal applicator (Influenza vaccine, live)

*Children and adolescents from 24 months:*

0.2 ml (administered as 0.1 ml per nostril).

For children who have not previously been vaccinated against seasonal influenza, a second dose should be given after an interval of at least 4 weeks. Fluenz Tetra should not be used in infants and toddlers below 24 months of age because of safety concerns regarding increased rates of hospitalisation and wheezing in this population.

Keep the nasal applicator in the outer carton in order to protect from light. Before use, the vaccine may be taken out of the refrigerator once 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 discarded.

Please refer to the appropriate product literature for correct dose: [www.medicines.org.uk/](http://www.medicines.org.uk/)

<table>
<thead>
<tr>
<th>3.5</th>
<th>Route/Method of Administration</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Administration of Influenza Vaccines is product specific and the information below in intended for general guidance only. Please refer to the appropriate product literature before administration.</td>
</tr>
</tbody>
</table>

**Administration of Inactivated Influenza Vaccine:**

- Immunisation should be carried out by intramuscular or deep subcutaneous injection, usually in the upper arm.
- Precautions to be taken before handling or administering the medicinal product:
  - The vaccine should be allowed to reach room temperature before use.
  - Shake before use. Inspect visually prior to administration.
  - If needed, for the administration of a reduced 0.25 ml dose from a single dose 0.5ml syringe, push the front side of the plunger exactly to the edge of the mark so that half of the volume is eliminated; a volume of 0.25ml of the vaccine remains in the syringe, suitable for administration. See also section 4.2.
  - Any unused product or waste material should be disposed of in accordance with local requirements.

**Storage:**

- Store in a refrigerator (+2°C to +8°C).
- Do not freeze.
- Store in the original package in order to protect from light.
Administration of Fluenz Tetra (Live attenuated Influenza nasal vaccine):

Fluenz Tetra IS FOR NASAL USE ONLY.

- DO NOT USE WITH A NEEDLE. Do not inject.

- Fluenz Tetra is administered as a divided dose in both nostrils.
- After administering half of the dose in one nostril, administer the other half of the dose in the other nostril immediately or shortly thereafter.
- The patient can breathe normally while the vaccine is being administered – there is no need to actively inhale or sniff.
- Refer to the Fluenz Tetra administration diagram (Figure 1) for step-by-step administration instructions.

Figure 1 Fluenz Tetra Administration

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.
### 3.6 Frequency of administration

Frequency of administration is product specific so please refer to the appropriate product literature.

Single dose administration unless otherwise stated on the product literature.

### 3.7 Duration of Treatment / Quantity supplied

Seroprotection is generally obtained within 2 to 3 weeks. The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

### 3.8 Side effects of drugs (to include potential Adverse Reaction)

**Reported side effects to Inactivated Influenza Vaccines:**

Adverse reactions reported from post marketing surveillance include the following:

- **Blood and lymphatic system disorders:**
  - Transient thrombocytopenia, transient lymphadenopathy

- **Immune system disorders:**
  - Allergic reactions, in rare cases leading to shock, angioedema

- **Nervous system disorders:**
  - Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome

- **Vascular disorders:**
  - Vasculitis associated in very rare cases with transient renal involvement

- **Skin and subcutaneous tissue disorders:**
  - Generalised skin reactions including pruritus, urticaria or non-specific rash

**Report side effects to Fluenz Tetra (Live attenuated Influenza nasal vaccine):**

The most common adverse reaction observed in clinical studies was nasal congestion/rhinorrhea.

**List of adverse reactions**

Adverse reaction frequencies are reported as:

- Very common (≥ 1/10)
In an active-controlled clinical study (MI-CP111), an increased rate of hospitalisations (for any cause) through 180 days after final vaccination dose was observed in infants and toddlers 6-11 months of age (6.1% Fluenz versus 2.6% injectable influenza vaccine). Most hospitalisations were due to gastrointestinal and respiratory tract infections and occurred more than 6 weeks post vaccination. The rate of hospitalisations was not increased in Fluenz recipients 12 months and older. In the same study, an increased rate of wheezing through 42 days was observed in infants and toddlers 6-23 months of age (5.9% Fluenz versus 3.8% injectable influenza vaccine). The rate of wheezing was not increased in Fluenz recipients 24 months and older. Fluenz Tetra is not indicated for use in infants and toddlers younger than 24 months (see section 4.2).

Very rare reports of Guillain-Barré syndrome and exacerbation of symptoms of Leigh syndrome (mitochondrial encephalomyopathy) have also been observed.

3.9 Procedure for reporting Adverse Drug Reaction's (ADR's) to Doctor

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

3.10 Written/verbal advice for patient/carer.

Patient to be given Patient Information Leaflet relating to the product prior to administration

3.11 Specify method of recording supply/administration, names of health professional, patient identifiers, sufficient to enable audit trail.

Electronic or paper health records as appropriate.
4. **Authorisation of Patient Group Direction**

   Developed and electronically authorised by:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>i.</td>
<td>Senior Doctor/ Consultant, QE Gateshead</td>
</tr>
<tr>
<td></td>
<td>Name: Frank McAuley</td>
</tr>
<tr>
<td>ii.</td>
<td>Representative of LPC</td>
</tr>
<tr>
<td></td>
<td>Name: Sami Hanna and Ann Gunning</td>
</tr>
<tr>
<td>iii.</td>
<td>Senior Pharmacist, QE Gateshead</td>
</tr>
<tr>
<td></td>
<td>Name: Mark Thomas</td>
</tr>
<tr>
<td>iv.</td>
<td>Chief Pharmacist, QE Gateshead</td>
</tr>
<tr>
<td></td>
<td>Name: Neil Gammack</td>
</tr>
</tbody>
</table>

The direction must be read, agreed to and signed by each of the health professionals who work within it. All professions must act within their appropriate Code of Professional Conduct.

5. **Patient Group Direction Copies to be available:**

   - Premise or clinical area where PGD is used
   - Headquarters of business if different from above
   - Pharmacists to have access to PGD (electronic or paper copy).
PGD: Administration of Influenza Vaccine for the 2015/16 influenza season

Name of Pharmacist: ___________________________ GPhC Registration Number: ___________________________

Competency assessment.

“On attendance and successful completion of the QE Gateshead Clinical Skills Training Programme, the pharmacist named above is deemed clinically competent to practice under this PGD.”

Declaration by Superintendent Pharmacist or Delegated Line Manager for Pharmacist named above:

“I have read and understood the PGD and authorise the pharmacist named above to operate in accordance with this PGD”.

Signature: ..........................  Date: ................................................

Declaration by Pharmacist working under this PGD.

- “I have read and understand this PGD;
- I have been appropriately trained to understand the criteria listed, and the techniques and record-keeping required to administer the vaccine in accordance with this PGD;
- I confirm that following my successful completion of the QE Gateshead Clinical Skills Training Programme, I am competent to undertake administration of this vaccine;
- I confirm that I will ensure that I remain up to date in all aspects of the administration of Influenza Vaccines for the purposes of this PGD.”

GPhC Registration Number: .......................... Expiry Date: ..........................

Signature: .......................... Date: ................................................

Disclaimer:
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 and in accordance with their own code of professional conduct.

Note: The authorising signatory should only authorise staff who have received the required training and are competent to work to this PGD. Each authorized member of staff should be provided with a copy of the PGD and signed authorization page. A copy of the signed authorization page should also be retained by the authorising signatory as a record of this agreement.
### Influenza vaccines for the 2015/16 influenza season

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Name of product</th>
<th>Vaccine type</th>
<th>Age indications</th>
<th>Ovaalbumin content µg/dose</th>
<th>Contact details</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca UK Ltd</td>
<td>Fluemz Tetra</td>
<td>Live attenuated, nasal</td>
<td>From 24 months to less than 16 years of age</td>
<td>≤1.2 (≤0.24/0.2ml dose)</td>
<td></td>
</tr>
<tr>
<td>GSK</td>
<td>Fluarix Tetra</td>
<td>Split virion inactivated virus</td>
<td>From three years</td>
<td>≤0.1 (≤0.05/0.5ml dose)</td>
<td>0800 221 441</td>
</tr>
<tr>
<td>MASTA</td>
<td>Agrippal</td>
<td>Surface antigen, inactivated virus</td>
<td>From six months</td>
<td>≤0.4 (≤0.2/0.8ml dose)</td>
<td>0113 236 7552</td>
</tr>
<tr>
<td></td>
<td>Influvax</td>
<td>Surface antigen, inactivated virus</td>
<td>From six months</td>
<td>0.2 (0.1/0.5ml dose)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Imuvax</td>
<td>Surface antigen, inactivated virus</td>
<td>From six months</td>
<td>0.2 (0.1/0.5ml dose)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inactivated influenza vaccine (Split Virion) BP</td>
<td>Split virion, inactivated virus</td>
<td>From six months</td>
<td>≤0.1 (≤0.05/0.5ml dose)</td>
<td></td>
</tr>
<tr>
<td>Mylan, formerly Abbott Healthcare</td>
<td>Influvax</td>
<td>Surface antigen, inactivated virus</td>
<td>From six months</td>
<td>0.2 (0.1/0.5ml dose)</td>
<td>0800 350 7466</td>
</tr>
<tr>
<td></td>
<td>Imuvax</td>
<td>Surface antigen, inactivated virus</td>
<td>From six months</td>
<td>0.2 (0.1/0.5ml dose)</td>
<td></td>
</tr>
<tr>
<td>Novartis Vaccines</td>
<td>Agrippal</td>
<td>Surface antigen, inactivated virus</td>
<td>From six months</td>
<td>≤0.4 (≤0.2/0.8ml dose)</td>
<td>08457 451 500</td>
</tr>
<tr>
<td>Pfizer Vaccines</td>
<td>bioCSL generic influenza vaccine</td>
<td>Split virion, inactivated virus</td>
<td>From five years</td>
<td>≤2 (≤1.5ml dose)</td>
<td>0800 089 4033</td>
</tr>
<tr>
<td></td>
<td>Enzira</td>
<td>Split virion, inactivated virus</td>
<td>From five years</td>
<td>≤2 (≤1.5ml dose)</td>
<td></td>
</tr>
<tr>
<td>Sanofi Pasteur MSD</td>
<td>Inactivated influenza vaccine (split virion) BP</td>
<td>Split virion, inactivated virus</td>
<td>From six months</td>
<td>≤0.1 (≤0.05/0.5ml dose)</td>
<td>0800 085 5511</td>
</tr>
<tr>
<td></td>
<td>Imnaza 15 micrograms</td>
<td>Split virion, inactivated virus</td>
<td>60 years of age and over</td>
<td>≤0.24 (≤0.02/0.1ml dose)</td>
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</tbody>
</table>

None of the influenza vaccines for the 2015/16 season contains thiomersal as an added preservative.

** In England, this vaccine should be ordered online via the ImmForm website (https://portal.immform.nhs.gov.uk/)

To subscribe to Vaccine Update: Click here To order immunisation publications: Click here
For vaccine ordering and supply enquiries, email: vaccinesupply@phe.gov.uk
Appendix 3:

Details of NHS Flu Plan 2015/16 High Risk Groups

NHS Flu Plan 2015/16 defines High Risk patient groups as follows:

• people aged 65 years or over (including those becoming age 65 years by 31 March 2016)

• people aged from six months to less than 65 years of age with a serious medical condition such as:
  - chronic (long-term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis
  - chronic heart disease, such as heart failure
  - chronic kidney disease at stage three, four or five
  - chronic liver disease
  - chronic neurological disease, such as Parkinson’s disease or motor neurone disease, or learning disability
  - diabetes
  - splenic dysfunction
  - a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)

• all pregnant women (including those women who become pregnant during the flu season)

• all those aged two, three, and four years (but not five years or older) on 31 August 2015 (i.e. date of birth on or after 1 September 2010 and on or before 31 August 2013).

• all children of school years 1 and 2.

• primary school-aged children in areas that participated in primary school pilots in 2014/15

• people living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions, or university halls of residence

• people who are in receipt of a carer’s allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill

• consideration should also be given to the vaccination of household contacts of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and, therefore, for whom continuing close contact is unavoidable

The list above is not exhaustive, and the healthcare practitioner should apply clinical judgement to take into account the risk of flu exacerbating any underlying disease that

Also recommended to be vaccinated as part of an employer’s occupational health obligation:

• health and social care workers with direct patient/service user contact

National NHS Flu Plan 2015/16:

More details of the 2015/16 National Flu Plan can be found at: www.gov.uk/government/organisations/public-health-england/series/immunisation

DoH Green Book:

Green Book chapter 19, “Influenza":