

**Seasonal flu vaccination programme for children: 2018/19**  
**An update for registered healthcare practitioners**  
**August 2018**

### **Background**

Following a recommendation in 2012 by the Joint Committee on Vaccination and Immunisation (JCVI) <sup>1</sup> that the seasonal flu programme should be extended to all children aged 2 to less than 17 years of age, the phased introduction of this extension began in October 2013.

### **Rationale of resource**

This resource is designed to support registered healthcare practitioners involved in raising the issue of flu vaccination with parents and carers, and providing evidence based information about flu vaccination. It only details the administration of the intranasal vaccine Fluenz™ Tetra.

This resource does not cover the actual administration techniques involved in vaccinating with any other flu vaccine.

If staff are required to deliver these vaccinations they should refer to their line manager for alternative training.

**Note:** For the purposes of this resource the term ‘influenza’ will be replaced by the term ‘flu’ unless it relates to a specific virus/strain.

# 2018/19 Programme

## No changes to programme

Resource changes: Changes to images of Fluenz™Tetra product in accordance with manufacturers SPC, Seasonal Flu vaccine programme algorithms for 2018/19 at end of this slide set

## **Seasonal Flu vaccination programme for children 2018/19**

### **Eligibility**

- In 2018/19, 2-5 year olds not yet in school (children must be aged 2 or above on 1 September 2018)
- All primary school aged children (primary 1-primary 7)
- With the exception of children in clinical risk groups at increased risk of complications, children in secondary school are not currently included in the programme

## **Seasonal flu vaccination programme to children 2018/19**

### **Green Book Chapter**

- Practitioners should ensure they are familiar with and refer to, the advice in the Green Book Chapter including contraindications and precautions before vaccinating patients

## Seasonal Flu vaccination programme for children 2017/18

### Influenza vaccine effectiveness in children in Scotland age 4-11 years measured by attendance at hospital: provisional end-of-season results for the 2015-16 season

- Estimated VE in children age 4-11 years reveals significant protection against both clinically diagnosed influenza (68%) and lab confirmed influenza (63%)
- These findings are consistent with recent estimates of flu VE in a general practice population in the UK\* and in Finnish 2 year old children\*\*

Source Health Protection Scotland

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\*Effectiveness of seasonal influenza vaccine in preventing laboratory-confirmed influenza in primary care in the United Kingdom: 2015/16 end of season results. Euro Surveill. 2016 Sep

\*\* Effectiveness of seasonal influenza vaccine in Finnish 2 year olds. Hannah Noyek paper Euro Surveill. 2016 Sep

### Key message

- In 2012 the Joint Committee on Vaccination and Immunisation (JCVI) recommended that the seasonal influenza (flu) programme should be extended to all children aged 2 to less than 17 years of age, the phased introduction began in October 2013
- It is hoped that this extension to the flu vaccination programme will reduce the impact of seasonal flu on children and reduce transmission of flu within the community
- Registered healthcare practitioners have a key role in promoting increased uptake of flu vaccination in children through increasing awareness

### Aims of resource

This resource aims to:

- Develop the knowledge base of registered healthcare practitioners regarding the extension of the flu vaccination programme to children
- Support registered healthcare practitioners involved in discussing flu vaccination for children with parents and carers by providing evidence based information
- Promote increased uptake of flu vaccination in children through increasing awareness of those involved in the vaccination programme
- Provide information on the administration of Fluenz™ Tetra

Key roles of registered healthcare practitioners in relation to the extension are as follows:

To understand the evidence base for the administration of the vaccination against flu to advise parents/carers of children who are eligible to receive the flu vaccination that it is strongly recommended that they are vaccinated against flu to safely administer flu vaccines including Fluenz™ Tetra in accordance with the vaccine schedule to ensure any adverse effects are managed and reported appropriately.

### Learning outcomes

On completion of this resource registered healthcare practitioners will be able to:

- Understand the evidence base for the administration of the vaccination against flu to children
- Describe the aetiology of flu
- Have an understanding of how flu is transmitted and the possible effects of flu on children
- Explain what vaccines will be used, the precautions and contraindications to the administration of flu vaccines
- Explain the possible side effects of administration of flu vaccines
- Explain the sequence of steps in Fluenz™ Tetra administration
- Identify sources of additional information
- Understand the importance of their role in raising the issue of vaccination with parents and carers of children and providing evidence based information about flu vaccination



## **Seasonal flu vaccination programme for children 2018/18**

### **Contents**

- Overview of current flu immunisation programme
- What is flu?
- Why extend the seasonal flu immunisation programme to all children?
- Vaccination of children against flu
- Resources
- References

## Current flu vaccination programme in Scotland

- In Scotland, there is an annual vaccination programme which aims to reduce the impact (morbidity and mortality) of flu particularly in high risk groups e.g. those aged 65 years or greater and those from age 6 months of age in clinical risk groups

## What is Flu?

## What is Flu?

Flu is a highly infectious viral illness?

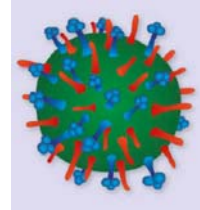
## Influenza viruses

There are 3 types of influenza viruses:

A	B	C
Causes epidemics and pandemics	May cause epidemics	Minor respiratory illness only
Animal reservoir – wildfowl and pigs, also carried by other mammals	Predominantly found in humans	

## Influenza A virus

- Genetic material (RNA) in the centre
- Two surface antigens:
  - Haemagglutinin (H)
  - Neuraminidase (N)
- Different types of each:
  - The blue protuberances represent haemagglutinin and the red spikes neuraminidase



### **Schematic model of an influenza A virus.**

There are two antigens on the surface, as illustrated.

The role of the H antigen is to bind to the cells of the host and there are 16 different types of H. The role of the N antigen is to release the virus from the cell surface and there are nine different types. The different types of H and N are identified by numbers, hence H1N1 for example.

## Influenza virus

### ***Genetic change – what this means***

#### Antigenic drift:

- Small constant mutations of H and N
- Most current flu vaccines protect against two strains of Flu A (H3N2) and A (H1N1) and one B strain (referred to as trivalent).
- However, two brands including Fluenz™ Tetra provide protection against two strains of flu A (H3N2) and A (H1N1) and two B strains (referred to as quadrivalent).

It is important to understand that flu viruses are constantly changing and to appreciate how this happens.

Influenza viruses lack proof-reading enzymes that maintain the fidelity of RNA replication and are therefore subject to high rates of mutation.

Antigenic drift: small mutations affecting the H and N antigens occur constantly. When changes enable the virus to multiply in an individual immune to previous strains, the new subtype can reinfect the community. This is because mutants emerge that express surface antigens (H and Ns) sufficiently different as to be unable to combine with existing antibody.

Throughout the last decade, there has generally been a good match between the strains of flu in the vaccine and those that subsequently circulate, so it's crucial that the issue of drifted strains seen last year do not discourage parents of children being offered Fluenz from having the vaccination now, or in the future. The vaccine effectiveness in most years is moderate and even if low has still been shown to ameliorate symptoms.

## Genetic change – what this means (cont.)

### Antigenic shift:

- Only occurs in Influenza A strains
- A major change in one or both surface antigens, characteristic of Influenza type A viruses
- It is due to genetic recombination when virus particles of more than one strain infect a cell simultaneously
- It can result in a worldwide pandemic

### **Antigenic shift**

Only occurs in Influenza A strain. A sudden major change occurs as a result of recombination of different virus cells when they infect the same cell. The new strain can then spread through a population immune to previous strains, and lead to a pandemic. This is what happened in 2009.

It will happen again!



### Features of flu

- Transmitted by large droplets, small-particle aerosols and by hand to mouth/eye contamination from an infected surface
- Incubation period 1-5 days (average 2-3 days) though may be longer especially in children and immunocompromised people
- Acute viral infection of respiratory tract

#### **Common symptoms include:**

- Sudden onset of fever, chills, headache, myalgia and severe fatigue
- Dry cough, sore throat and stuffy nose
- In young children gastrointestinal symptoms such as vomiting and diarrhoea may be frequently seen

In healthy individuals it is usually unpleasant but self-limiting with recovery within 5-7 days.

## Possible complications of flu

### Common:

- Bronchitis
- Otitis media (children), sinusitis

### Less common:

- Secondary bacterial pneumonia
- Meningitis, encephalitis
- Primary influenza pneumonia
- Most serious illness in neonates, pregnant women, older people and those with underlying disease

# Why extend the seasonal flu vaccination programme to children?

## Why vaccinate children?

Extension of the seasonal flu vaccination programme to all children aims to appreciably lower the public health impact of flu by:

- Providing direct protection to children thus averting a large number of cases of influenza disease in this group
- Lowering influenza transmission from:
  - Child to child
  - Child to adult
  - Child to those in the clinical risk groups of any age

The expected effect of the vaccination of children will then be a reduction in both the morbidity and mortality associated with flu (direct and indirect effect).

The JCVI position statement on the extension of the annual flu vaccination programme to children can be found at:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/224775/JCVI-statement-on-the-annual-influenza-vaccination-programme-25-July-2012.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/224775/JCVI-statement-on-the-annual-influenza-vaccination-programme-25-July-2012.pdf)

And / or:

<http://webarchive.nationalarchives.gov.uk/20120907090205/http://transparency.dh.gov.uk/2012/07/25/jcvi-meeting-june-2012/>

JCVI Statement August 2016

<https://www.gov.uk/government/publications/jcvi-statement-on-the-nasal-spray-flu-vaccine>

### **Cost effectiveness**

Studies commissioned by the JCVI<sup>3</sup> suggest that despite the high cost, extending the flu vaccination programme to healthy children is:

- Highly likely to be cost-effective
- Is well below the established cost-effectiveness threshold when indirect protection to the whole population is taken into account, particularly over the longer-term
- Remains cost effective in circumstances where vaccine uptake by clinical risk groups was substantially increased

## Recent observation/studies relating to flu and children

Clinical trials on effectiveness of live attenuated influenza vaccine (LAIV):

- Single dose of LAIV provides similar protection to children as two doses of inactivated influenza vaccine<sup>4,5</sup>
- Second dose of LAIV provides modest additional protection against flu infection (e.g. 60% v. 77% vaccine effectiveness for one and two doses, respectively)<sup>4</sup>

1. Evidence from clinical trials on the effectiveness of one and two dose schedules of live attenuated flu vaccine (LAIV) in flu vaccine-naïve young children shows a second dose of LAIV provides modest additional protection against flu (e.g. 60% versus 77% vaccine effectiveness for one and two doses, respectively<sup>4</sup>) and that a single dose of LAIV may provide similar protection to children as two doses of inactivated flu vaccine.<sup>4,5</sup>

2. Analysis of the difference in the population health impact and the cost effectiveness of one and two dose schedules of LAIV for flu vaccine-naïve children aged up to nine years when extending the programme to all pre-school children from two years of age and primary school-aged children and an analysis of the direct health impact only of either two doses of LAIV to two year old children or one dose to two and three year old children suggests that the greater health impact would be obtained if the available quantity of vaccine was provided through a one dose schedule to the larger number of children with two doses reserved for those children under the age of nine who are in a clinical group at increased risk of complications.

### Recent review of burden of flu in children

- Average flu season: estimated 0.3% to 9.8% of 0-14 year old children present to a GP with influenza<sup>7</sup>
- Incidence rates can be markedly higher in the younger age groups
- Flu associated hospitalisation rates: <sup>8, 9, 10, 11, 12</sup>
  - 83-1038 / 100000 children 0-59 months old (highest in <6 months)
  - 16-210/100000 children 5-17 years
- Children more vulnerable to infection than adults when exposed. <sup>13, 14</sup>
- Children with flu contribute to the burden of flu in all age groups because they are more likely to pass on the infection than adults <sup>14, 15</sup>

These figures are based on published evidence of flu burden in children worldwide. <sup>7</sup>

## What is the additional evidence to support the offer of vaccination?

- Trivalent inactivated vaccine (TIV) shown to be effective in eliciting a protective antibody response/averting flu like illness, when a two dose schedule is used for vaccine naïve children <sup>16,22,24,25</sup>
- Live attenuated flu vaccine (LAIV) ~ 50% more effective than TIV in averting laboratory confirmed influenza <sup>17,18</sup>
- Meta-analysis of six LAIV studies showed median VE of 78% (range: 57-93) in children 6 months to 7 years <sup>23</sup>
- One dose of LAIV provides clinically significant protection against flu in young flu vaccine naïve children, with a second dose providing additional protection. Up to 90% of protection are conferred by the first dose <sup>19, 20</sup>
- LAIV is well tolerated in children and adolescents with asthma <sup>21,26</sup>



## Vaccination of children against flu

## Types of vaccines

Two main types of vaccine:

- Inactivated - by intramuscular injection
- Live - by nasal application

Antibody levels may take 14 days to reach protective levels  
Protection lasts for at least one season.

Due to the changing nature of Influenza viruses in February of each year the World Health Organisation recommends the viruses that should be in the vaccine for the forthcoming winter. Quadrivalent vaccines with an additional type of B virus have been developed and have been available in the UK since 2013.

For many years only inactivated flu vaccines given by intramuscular injection have been available in the UK. These give 70 to 80% protection when the vaccine strains are well matched to those circulating. They are less protective in the elderly but still significantly reduces bronchopneumonia, hospitalisations and mortality.

Trivalent live attenuated flu vaccine has been shown to provide a higher level of protection for children than trivalent inactivated flu vaccine; <sup>18</sup> a recent meta-analysis suggested an efficacy against confirmed disease of 83% (95% confidence interval 69-91).<sup>17,21,23</sup>

For those children for whom Fluenz™ Tetra is unsuitable, quadrivalent inactivated flu vaccine should be offered. In children aged from 6 months, quadrivalent inactivated vaccine should be offered. Some brands are restricted to use in particular age groups. Practitioners must be familiar with and refer to the marketing authorisation holder's SPC for the particular brand before administering vaccines.

## Use of Fluenz™ Tetra

## Use of Fluenz™ Tetra

### Fluenz™ Tetra:

- Generic name: influenza vaccine (live attenuated, nasal)
- Brand name: Fluenz™ Tetra
- Marketed by AstraZeneca
- Licensed from 24 months to less than 18 years of age
- Nasal Spray (suspension) in a prefilled nasal applicator
- Supplied as pack containing 10 doses
- Container dimensions: 117.5 x 115.5 x 36mm
- Provides greater protection for children than inactivated influenza vaccine

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Fluenz™ Tetra is a live attenuated vaccine (a weakened form of flu virus which cannot cause disease but which protects against flu). It is a cold adapted virus which means it cannot replicate at body temperature.

This is a nasal vaccine and **must not be injected**.

It is supplied in a box containing 10 prefilled nasal applicators.

The vaccine was procured following a tendering exercise undertaken by the Department of Health on behalf of UK nations and ensured the vaccine was available at a cost-effective price.


Live attenuated flu vaccine (Fluenz™ Tetra) has been shown to provide greater protection for children than inactivated flu vaccine. This vaccine is the preferred vaccine for children aged two to less than 18 years.

It became available in the UK for the 2012/13 flu season. It has been used in USA for many years and millions of doses have been given.

Fluenz® was used from October 2013 during phase one of the extension to the flu programme in children. From October 2014, Fluenz™ Tetra has been used.

## Use of Fluenz™ Tetra (cont.)

### Fluenz™ Tetra composition

Active Ingredient	Excipients	Residues
A/Michigan/45/2015(H1N1)pd m09-like virus	Sucrose	Egg proteins (e.g. ovalbumin)
A/Singapore/INF1MH-16-0019/2016 (H3N2)-like virus	Dibasic potassium phosphate	Gentamicin
B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage)	Monobasic potassium phosphate	
B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage)	Gelatin (porcine type A)	
	Arginine hydrochloride	
	Monosodium glutamate monohydrate	
	Water for injection	

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The vaccine complies with the WHO recommendation (Northern Hemisphere) and the EU decision for the **2018/19** season.

The virus strains are produced in Vero cells (monkey cell line) and grown in fertilised hens' eggs from healthy chicken flocks.

Fluenz™ Tetra does not contain any preservatives such as thiomersal.

The vaccine is supplied in a single use nasal applicator (type I glass), with nozzle (polypropylene with polyethylene transfer valve), nozzle tip-protector (synthetic rubber), plunger rod, plunger stopper (butyl rubber) and dose divider clip which should not affect latex sensitive individuals.

### Use of Fluenz™ Tetra (cont.) Fluenz™ Tetra presentation

- Prefilled nasal applicator
- Nasal spray (suspension)
- Each applicator contains 0.2ml



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The applicator may look slightly different for 2018-19 due to changes by the manufacturer.

## Use of Fluenz™ Tetra (cont.)

### Storage of Fluenz™ Tetra

- Fluenz™ Tetra must be stored in accordance with manufacturer's instructions:
  - Store between +2°C and +8°C
  - Store in original packaging
  - 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 disposed of in accordance with local procedures for disposal of clinical waste
- **Check expiry dates regularly:**
  - Fluenz™ Tetra has an expiry date 18 weeks after manufacture – this is much shorter than inactivated flu vaccines

Fluenz™ Tetra must be stored in accordance with the manufacturers instructions. As with most vaccines Fluenz™ Tetra should be stored between +2°C and +8°C.

The vaccine should be stored in the original packaging. This makes it easy to identify in the vaccine fridge and to check batch numbers and expiry dates. The original packaging also provides some protection against fluctuation of temperature and protection 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 disposed of.

Vaccine are expensive and it is important to minimise wastage through inappropriate storage.

### Use of Fluenz™ Tetra (cont.)

#### Fluenz™ Tetra dosage and schedule

- A single dose is 0.2ml (administered as 0.1ml per nostril)
- A single dose for all children **not** in clinical at risk group
- Children aged less than nine years who are in clinical at risk groups and who have not received flu vaccine before should receive two doses of Fluenz™ Tetra with the second dose at least four weeks after the first  
If the first dose is given in school the second dose will be given according to local NHS board arrangements.

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The dose of Fluenz™ Tetra is 0.2ml, administered as a divided dose (0.1ml) in both nostrils. After administering half of the dose in one nostril, administer the other half in the other nostril immediately or shortly thereafter.

Children who are not in a clinical at risk group require a single dose (0.2ml).

The marketing authorisation holder's Summary of Product Characteristics (SmPC) states that all children under nine years old receiving flu vaccine for the first time require two doses, with second at least four weeks after the first. The JCVI have considered this issue and have advised that in children who are not in a clinical at risk group a single dose of Fluenz™ Tetra is recommended.

Registered healthcare practitioners are reminded that in some circumstances the recommendations regarding vaccines given in the Green Book chapters may differ from those in the SmPC for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and this advice should be followed.

The Green Book recommendations and/or further advice from the Department of Health should be reflected in PGDs.

However children aged under nine years of age in clinical at risk groups and who are receiving flu vaccine for the first time will require the two dose schedule. If the first dose is given in school the second dose will be given according to local NHS board



arrangements

## Administration of Fluenz™ Tetra

- Fluenz™ Tetra is different from other flu vaccines, it is a **live intranasal vaccine**
- Fluenz™ Tetra **must not be injected**
- Fluenz™ Tetra **can be** administered at the same time as other vaccines including live vaccines
- Patient should breathe normally - no need to actively inhale or sniff
- No need to repeat either half of dose if patient sneezes, blows their nose or their nose drips following administration

Fluenz™ Tetra can be given at the same time as 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, JVICI have advised that no specific intervals need to be observed between Fluenz™ Tetra and other live vaccines.

## Administration of Fluenz™ Tetra (cont.)

The vaccine may only be administered:

- Against a prescription written manually or electronically by a registered medical practitioner or other authorised prescriber:
  - Against a **Patient Specific Direction**
  - Against a **Patient Group Direction**

## Administration of Fluenz™ Tetra Video

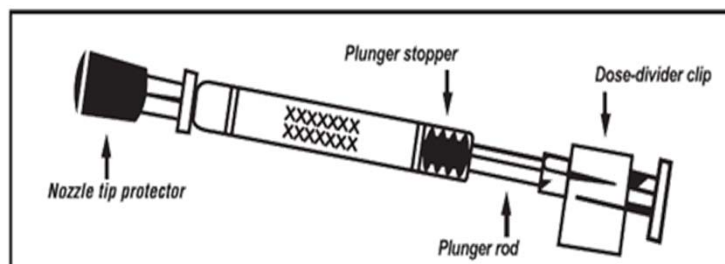
### Video clip showing administration

Click on the following link to access the video clip showing how to administer Fluenz™ Tetra vaccine:

<https://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/seasonal-flu/childhood-seasonal-flu-vaccination-programme-resources-for-registered-practitioners.aspx>



### Fluenz™ Tetra Applicator

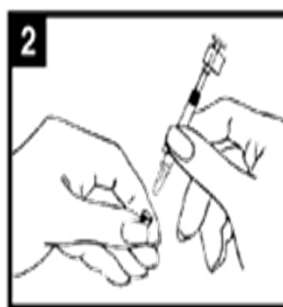
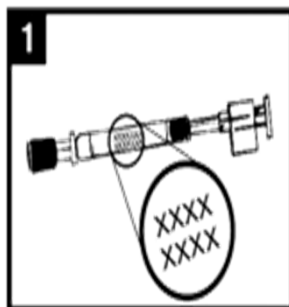


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Image from electronic Medicines Compendium. SmPC (summary of product characteristics) Fluenz Tetra. <https://www.medicines.org.uk/emc/product/3296/smpc> Accessed 18<sup>th</sup> July 2018

## Administration of Fluenz™ Tetra

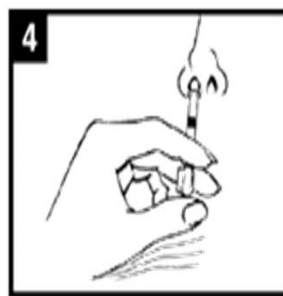
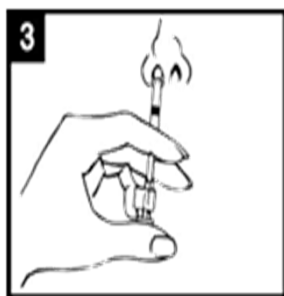


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1. Check the expiry date - the vaccine must be used before the date on the applicator label.
2. Prepare the applicator - remove the rubber tip protector. **Do not remove the dose divider clip at the other end of the applicator.**

### Administration of Fluenz™ Tetra (cont.)



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3. Position the applicator – with the patient in an up right position, place the tip just inside the nostril to ensure Fluenz™ Tetra is delivered into the nose.
4. Depress the plunger – with a single motion, depress the plunger **as rapidly as possible until the dose-divider clip prevents you from going further.**

Image from electronic Medicines Compendium. SmPC (summary of product characteristics) Fluenz Tetra. <https://www.medicines.org.uk/emc/product/3296/smpc>  
Accessed 18<sup>th</sup> July 2018

### Administration of Fluenz™ Tetra (cont.)



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5. Remove the dose-divider clip – for administration in the other nostril, pinch and remove the dose-divider clip from the plunger.

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements for medical waste.

Image from electronic Medicines Compendium. SmPC (summary of product characteristics) Fluenz Tetra. <https://www.medicines.org.uk/emc/product/3296/smpc>  
Accessed 18<sup>th</sup> July 2018



## Use of Fluenz™ Tetra

### Infection control issues:

- There are no specific infection control precautions required when administering Fluenz™ Tetra
- Routine hand hygiene procedures should be performed before and after each child contact
- As a precaution, very severely immunosuppressed individuals should not administer live attenuated flu vaccine
- Other healthcare workers who are immunosuppressed or pregnant, should follow normal clinical practice to avoid inhaling the vaccine and ensure that they are appropriately vaccinated

### Disposal of clinical waste:

- Empty Fluenz™ Tetra vaccines should be disposed of in accordance with local procedures for disposal of clinical waste

Advice in Standard Infection Control Precautions (SCIPs) would suggest no additional infection control precautions are required when administering Fluenz™ Tetra vaccine. Comprehensive infection control advice is available on HPS website at <http://www.nipcm.hps.scot.nhs.uk/chapter-1-standard-infection-control-precautions-sicps/>

There may be some inadvertent low level exposure of those administering live attenuated influenza vaccine to the vaccine viruses.

In the US, where there has been extensive use of the live attenuated influenza vaccine, there have been no reported instances of illness or infections from the vaccine virus among those healthcare professionals or immunocompromised patients inadvertently exposed. Thus, the Centers for Disease Control and Prevention has considered that the risk of acquiring vaccine viruses from the environment is unknown but is probably low. As the vaccine viruses are cold-adapted and attenuated, there are unlikely to cause symptomatic influenza.

Nevertheless, as a precaution, very severely immunosuppressed individuals should not administer live attenuated flu vaccine. Other healthcare workers who are immunosuppressed or pregnant, should follow normal clinical practice to avoid inhaling the vaccine and ensure that they are appropriately vaccinated.

To ensure the correct disposal of Fluenz™ Tetra vaccine applicators contact should be made with local NHS Board Waste Management Officer for advice.

## Use of Fluenz™ Tetra Contraindications

- Age under 2 years
- Age 18 years or above
- Confirmed anaphylactic reaction to a previous dose of flu vaccine
- Confirmed anaphylactic reaction to any component of the vaccine (except for ovalbumin [egg protein])

There are very few individuals who cannot receive any flu vaccine. When there is any doubt, appropriate advice should be sought from an immunisation coordinator or appropriate person e.g. Consultant in Public Health Medicine (CPHM) rather than withholding vaccination

## Use of Fluenz™ Tetra Contraindications (contd.)

- Severe immunosuppression due to conditions or immunosuppressive therapy:
  - Acute and chronic leukaemias
  - Lymphoma
  - HIV positive patient not on highly active antiretroviral therapy
  - Cellular immune deficiencies
  - High dose steroids
- Individuals receiving salicylate therapy (other than for topical treatment of localised conditions)
- Known to be pregnant

In cases of contraindication as a result of immunosuppression, severe asthma, wheezing within last 72 hours or increased bronchodilator use in the last 72 hours at time of immunisation (covered in subsequent slides), pregnancy or salicylate therapy, consider use of the inactivated (i.e. injectable) flu vaccine.

Chapter 6 of the Green Book on contraindications and special considerations contains further advice on the use of live vaccines in individuals who are severely immunosuppressed.

Chapter 6 also suggests systemic high dose steroids (and until at least three months after treatment has stopped) would include children who receive prednisolone, orally or rectally, at a daily dose (or it's equivalent) of 0.2mg/kg for at least one week, or 1mg/kg/day for one month.

Fluenz Tetra is not contraindicated for use in children or adolescents with HIV infection receiving stable antiretroviral therapy; or who are receiving topical/inhaled corticosteroids or low dose systemic corticosteroids or those receiving corticosteroids as replacement therapy, e.g. for adrenal insufficiency.

Inactivated flu vaccines are preferred for those aged under 18 who are pregnant. There is no need to specifically test girls for pregnancy or to avoid pregnancy in those who have been recently vaccinated.

## Administration of Fluenz™ Tetra Precautions

- **Acute severe febrile illness**
  - defer until recovered
- **Heavy nasal congestion**
  - defer until resolved or consider inactivated influenza vaccine

**Please note: Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination**

Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If the individual is acutely unwell the vaccination may be deferred until they have recovered - this is to avoid confusing the differential diagnosis of acute illness by wrongly attributing the signs or symptoms as adverse effects of the vaccine.

There are no data on the effectiveness of Fluenz™ Tetra when given to children with heavily blocked or runny nose (rhinitis) attributable to infection or allergy. As heavy nasal congestion might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration until resolution of the nasal congestion should be considered or an appropriate alternative intramuscularly administered flu vaccine should be considered.

### **Administration of Fluenz™ Tetra Precautions (cont.)**

- Fluenz™ Tetra should not be administered at the same time as use with antiviral agents against flu
- Fluenz™ Tetra should not be administered within 48 hours of 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

## Fluenz™ Tetra - Egg Allergy

- Except for these with severe anaphylaxis to egg which has previously required intensive care, children with an egg allergy can be safely vaccinated with Fluenz™ Tetra in any setting (including primary care and schools)\*
- Those with clinical risk factors that contraindicate Fluenz™ Tetra should be offered an inactivated influenza vaccine with a very low ovalbumin content (less than 0.12micrograms/ml)

\* Green book chapter -Those with clinical risk factors that contraindicate Fluenz™ Tetra will be offered an inactivated influenza vaccine by the registered healthcare practitioner.

## Severe Asthma and active wheezing

In cases of severe asthma or active wheezing:

- **Fluenz™ Tetra is not recommended:**
  - for children currently taking oral steroids
  - prescribed oral steroid in the last 14 days
- **Fluenz™ Tetra should only be given on the advice of a specialist** for children currently taking high dose of an inhaled steroid such as Budesonide greater than 800 micrograms/day or equivalent

There is limited safety data on children who are currently taking a high dose of an inhaled steroid (Budesonide > 800 micrograms/day or equivalent (e.g. Fluticasone > 500 micrograms/day) - such children should only be given LAIV on the advice of their specialist. As these children are a defined risk group for influenza, those who cannot receive LAIV should receive an inactivated influenza vaccine.

### Severe Asthma and active wheezing (Contd.)

- Fluenz™ Tetra should be deferred in:
  - children with a history of active wheezing in the past 72hrs
  - children who have increased their use of bronchodilators in previous 72hrs

Vaccination with Fluenz tetra should be deferred in children with a history of active wheezing in the past 72 hours or those who have increased their use of bronchodilators in the previous 72 hours. If their condition has not improved after a further 72hrs then, to avoid delaying protection in this high risk group, these children should be offered an inactivated influenza vaccine.

#### JCVI 2015

Children with a history of severe anaphylaxis to egg which has previously required intensive care, should be referred to specialists for immunisation in hospital. Children in a clinical risk group and aged under nine years who have not been previously vaccinated against influenza will require a second dose whether given LAIV or inactivated vaccine.



## Administration of Fluenz™ Tetra

### Risk of transmission:

- 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
- However, where close contact with very severely immunocompromised patients (e.g. bone marrow transplant patients requiring isolation) is likely or unavoidable (e.g. household members) an appropriate alternative inactivated influenza vaccines should be considered

In the US, where there has been extensive use of live attenuated vaccine, there have been no reported instances of illness or infections from the vaccine virus among immunocompromised patients inadvertently exposed.

## Fluenz™ Tetra -Suspected adverse reactions

The most common adverse reactions following administration of Fluenz™ Tetra were:

- nasal congestion/rhinorrhoea
- reduced appetite
- weakness
- headache

The full list of adverse reactions associated with Fluenz™ Tetra is available in the marketing authorisation holder's Summary of Product Characteristics.

Although uncommon some children may experience a nosebleed after administration of Fluenz™ Tetra.

Anaphylaxis is a very rare adverse effect of most vaccines and facilities for its recognition and management must be available.

## Administration of Fluenz™ Tetra and pork gelatin

- Fluenz™ Tetra contains pork (porcine) gelatin, an essential ingredient in many medicines, including some vaccines
- Many faith groups have approved the use of gelatin-containing vaccines
- It is, however, an individual choice whether or not to receive this vaccine and we recognise there will be diversity of thought within different communities

Those who choose not to have Fluenz™ Tetra for faith reasons may request the injectable alternative.

Vegetarians should also note that pork gelatin is an ingredient in the vaccine.

## Reporting suspected adverse reactions

### Yellow card scheme

- Voluntary reporting system for suspected adverse reaction to medicines/vaccines
- Success depends on early, complete and accurate reporting
- Report even if uncertain about whether vaccine caused condition
- See: <http://mhra.gov.uk/yellowcard>
- See chapter 8 of Green Book for details



As with all vaccines and other medicines registered healthcare practitioners and patients are encouraged to report suspected adverse reactions using the Yellow Card reporting scheme.

Fluenz™ Tetra is a black triangle medicine. This is a standard symbol added to the product information of a vaccine during the earlier stages of its introduction, to encourage reporting of all suspected adverse reactions.

# Use of Inactivated Flu Vaccine

## Use of inactivated flu vaccine

### Presentation:

- Supplied as pre-filled syringe
- Must be shaken before they are administered

### Storage:

- Store between +2°C and +8°C, in original packaging, protected from light

### Quadrivalent inactivated vaccine

- Recommended for children from six months for whom Fluenz™ Tetra is not suitable

### Age restrictions:

- Some flu vaccines are restricted to use in particular age groups. Practitioners must be familiar with and refer to the summary of product characteristics for the particular brand when administering vaccines

Children from six months to under 2 years and children aged from two years for whom Fluenz Tetra is not suitable should be offered quadrivalent inactivated influenza vaccine. Some inactivated flu vaccines are restricted to use in particular age groups. Practitioners must be familiar and refer to the marketing authorisation holder's SPC for the particular brand when administering vaccines.

## Use of inactivated flu vaccine (cont.)

### Contraindications, precautions and adverse reactions

Contraindications	Precautions	Adverse Reactions
Confirmed anaphylactic reaction to flu vaccine	Acute severe febrile illness defer until recovered	Pain, swelling, redness at injection site
Confirmed anaphylactic reaction to any component of the vaccine (other than ovalbumin [egg protein])		Low grade fever, malaise, shivering, fatigue, headache, muscle pain and joint pain

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There are very few individuals who cannot receive any flu vaccine. When there is any doubt, appropriate advice should be sought from an Immunisation Coordinator or Consultant in Public Health Medicine (CPHM) rather than withholding vaccination.

Inactivated flu vaccine should be considered when the patient cannot receive Fluenz™ Tetra due to immunosuppression, severe asthma, **wheezing within last 72 hours or increased bronchodilator use in the last 72 hours at time of immunisation, pregnancy** or salicylate therapy.

Inactivated flu vaccine has a very similar adverse reaction profile as Fluenz™ Tetra - the main difference is that with inactivated flu virus is the most common adverse reaction is a local injection site reaction. This usually disappears after 1-2 days.

Advice from the Green Book on managing patients with egg allergy should be followed.

Patients with egg allergy can be immunised with an egg-free flu vaccine if available. If no egg-free vaccine is available, patients should be immunised in primary care using an inactivated flu vaccine with an ovalbumin content less than 0.12microgramsg/ml(equivalent to0.06micrograms for 0.5ml dose). Vaccines with ovalbumin content more than 0.12micrograms/ml (equivalent to 0.06micrograms for 0.5ml dose) or where content is not stated should not be used in egg-allergic individuals. Only patients who have either confirmed anaphylaxis to egg or egg allergy with severe uncontrolled asthma (see Green Book for definition) should be referred to specialists for immunisation in hospital. Facilities should be available and staff trained to recognise and

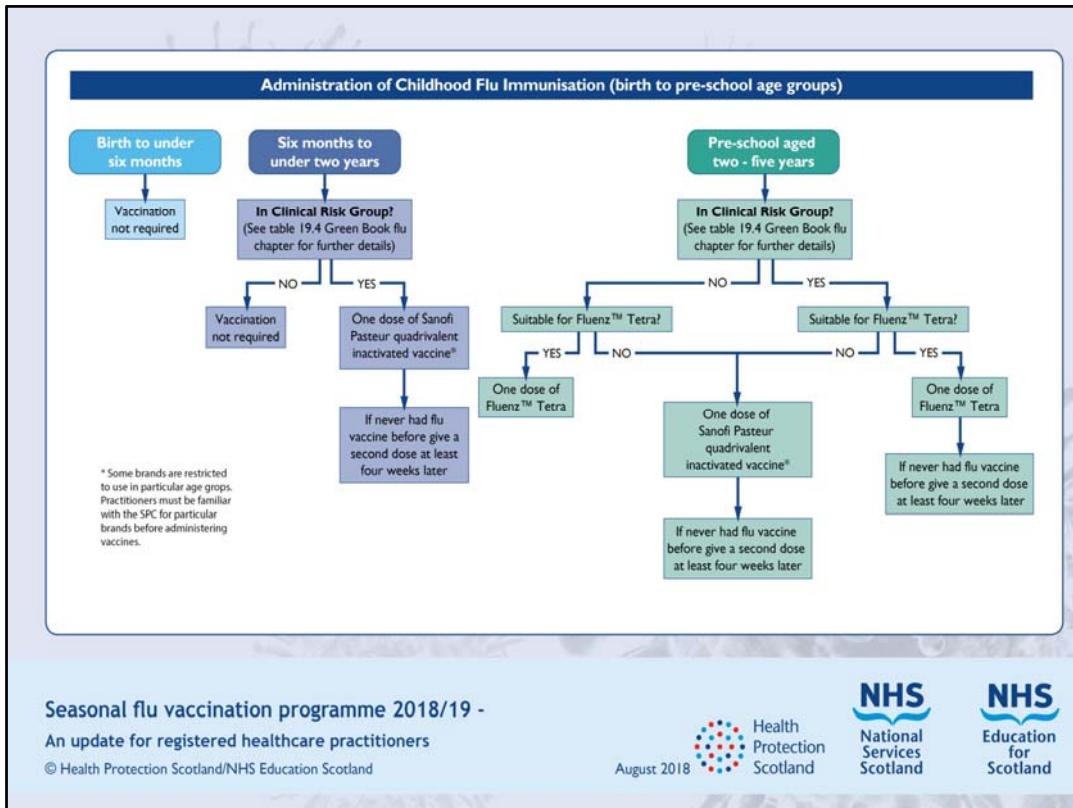
treat anaphylaxis (see chapter 8).

The ovalbumin content of the influenza vaccine will be published prior to the influenza season.



## Reporting

- Aggregate level data on vaccine uptake will be available on a 4 weekly basis. This will be provided on an all Scotland basis with additional information provided to each NHS board
- End of season vaccination uptake data will be provided in a more detailed analysis



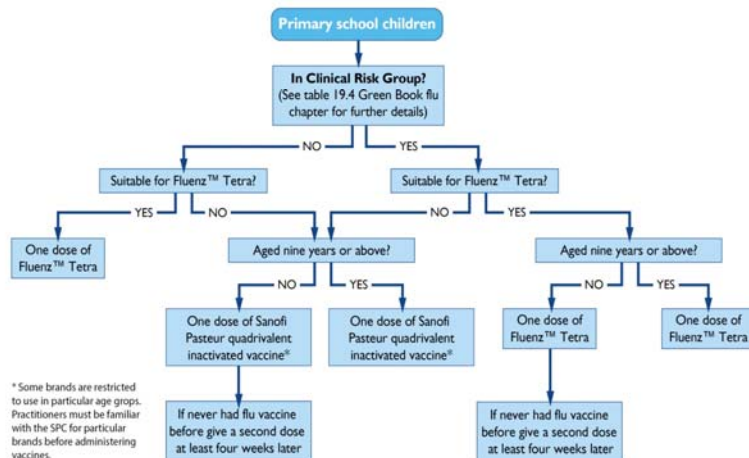
**Seasonal flu vaccination programme 2018/19 -**

An update for registered healthcare practitioners

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### Administration of Childhood Flu Immunisation (primary school age group)



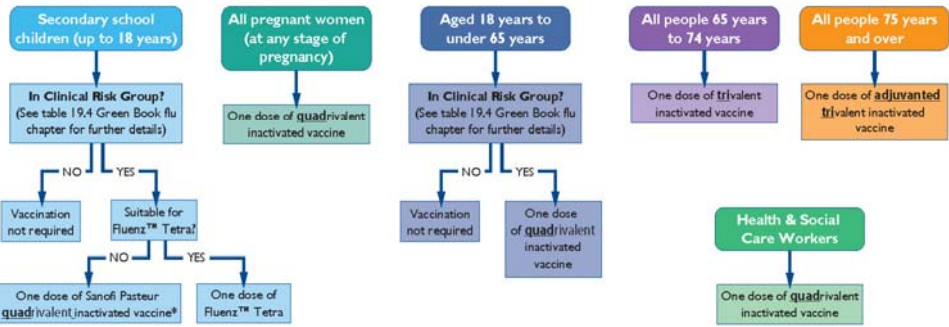
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**Administration of flu immunisation**  
(secondary school, all adult age groups at risk, pregnant women and other special risk groups)



\* Some brands are restricted to use in particular age groups. Practitioners must be familiar with the SPC for particular brands before administering vaccines.

**Seasonal flu vaccination programme 2018/19 -**

An update for registered healthcare practitioners

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### Resources

**Green Book**

<http://www.gov.uk/government/publications/influenza-the-green-book-chapter-19>

**CMO letter**

<http://www.sehd.scot.nhs.uk/index.asp?name=&org=%25&keyword=&category=9&number=10&sort=tDate&order=DESC&Submit=Go>

**NHS Inform**

<https://www.nhsinform.scot/healthy-living/immunisation/vaccines/flu-vaccine>

**Patient Group Directions**

<http://www.hps.scot.nhs.uk/immvax/pgd.aspx> replace with

<http://www.hps.scot.nhs.uk/resp/seasonalinfluenza.aspx?subjectid=00#vaccine>

**Policy for the Storage and Handling of Vaccines**

<http://www.hps.scot.nhs.uk/resourcedocument.aspx?id=206>

**NES website**

[http://www.nes.scot.nhs.uk/education-andtraining/by-theme\\_initiative/public-health/healthprotection/seasonal-flu.aspx](http://www.nes.scot.nhs.uk/education-andtraining/by-theme_initiative/public-health/healthprotection/seasonal-flu.aspx) - this link isn't working!

Any registered healthcare practitioner who administers vaccines should be familiar with the Green Book available at: <http://www.gov.uk/government/publications/influenza-the-green-book-chapter-19>.

Part 1 includes 12 chapters, the content of which is generic.

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Images from electronic Medicines Compendium. SmPC (summary of product characteristics) Fluenz™ Tetra.

<https://www.medicines.org.uk/emc/product/3296/smpc> Accessed 18<sup>th</sup> July 2018

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