

## **PATIENT GROUP DIRECTION (PGD)**

**Administration of Fluenz<sup>®</sup> nasal spray suspension (influenza vaccine, live)**

Infants, children and adolescents aged 2–17 years

For the supply of Fluenz<sup>®</sup> nasal spray suspension (influenza vaccine, live) by nurses currently registered with the Nursing and Midwifery Council (NMC) to infants, children and adolescents aged 2–17 years.

Reference no: Fluenz<sup>®</sup> PGD

Version no: final

Valid from: *1<sup>st</sup> September 2013*

Review date: *3<sup>1st</sup> August 2014*

Expiry date: *31<sup>st</sup> August 2015*

**Public Health England is not a legal authority for the authorisation of PGDs.**

Each organisation using this PGD must ensure that it is formally authorised and signed by a governance lead for the organisation so that this document meets legal requirements for a PGD. The PGD is not legal or valid without this local, formal authorisation.

**THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**

This Patient Group Direction has been produced by Public Health England to assist organisations such as NHS England Area Teams or others to develop and authorise a PGD that is consistent with current national guidance.

# 1. Clinical condition or situation to which the direction applies.

<b>Indication</b>	Fluenz® is indicated, unless it is unsuitable, for the active immunisation of infants, children and adolescents aged 2 to 17 years for the prevention of influenza infection, in line with the recommendations given in <a href="#">Chapter 19</a> of the <i>Immunisation Against Infectious Disease: The Green Book</i> .
<b>Objective of programme</b>	The ultimate objective of the extended influenza vaccination programme is to provide a single dose of Fluenz® vaccine to infants and children from 2 years to <b>less than</b> 17 years of age who are not in a risk category and in order to prevent symptoms and spread of infection with influenza virus. However, for the first year (2013-14) this extended programme is limited to those children aged two to three years on 1 <sup>st</sup> September 2013
<b>Criteria for inclusion</b>	<p>In this first year of the extended influenza vaccination programme Fluenz® vaccination will be offered to</p> <ul style="list-style-type: none"> <li>• all infants aged two years and three years (but not four years or older) on 1 September 2013 and</li> <li>• children aged four to ten years (up to and including pupils in school year 6) in a small number of pilot areas</li> </ul> <p>Fluenz® is also the influenza vaccine of choice, unless it is unsuitable, for children aged 4 to 17 years who are in a clinical risk group category listed in <a href="#">Chapter 19</a> of the <i>Immunisation Against Infectious Disease: The Green Book</i>. This is because Fluenz® provides greater protection for children than inactivated influenza vaccine. See section on <a href="#">Dose</a> below.</p>
<b>Criteria for exclusion<sup>1</sup></b>	<p><b>Infants aged under 2 years</b></p> <p>Fluenz® should NOT be given to infants under 2 years of age</p> <p><b>Children aged 4 to 10 years</b></p> <p>During the influenza vaccination season 2013-14, Fluenz® will only be given to those of this age group who are in one of the pilot areas or because they are in a clinical risk group category listed in <a href="#">Chapter 19</a> of the <i>Immunisation Against Infectious Disease: The Green Book</i>.</p> <p><b>Children and adolescents aged 11 to less than 18 years</b></p> <p>During the influenza vaccination season 2013-14, Fluenz® should only be given to children who are eligible for influenza</p>

<sup>1</sup> 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

vaccination because they are in a clinical risk group category, as above. See [Criteria for Inclusion](#) above.

#### **Adults aged 18 years and older**

Fluenz® should NOT be given to adults.

In addition Fluenz® should NOT be given to:

Individuals with a confirmed anaphylactic reaction to a previous dose of influenza vaccine;

Individuals with a confirmed anaphylactic reaction to any component of the Fluenz® vaccine;

Individuals with severe asthma (BTS SIGN step 4 or above);

Individuals with confirmed anaphylaxis to egg. Note: There are no data on the use of Fluenz® in children with egg allergy.

Individuals receiving salicylate therapy. This is because of the association of Reye's syndrome with salicylates and wild-type influenza infection;

Pregnant teenagers. 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.

#### **Immunosuppression**

Children or adolescents who are clinically severely immunodeficient due to conditions or immunosuppressive therapy such as: acute and chronic leukaemias; lymphoma; HIV infection not on highly active antiretroviral therapy (HAART); cellular immune deficiencies or high dose corticosteroids

(at least 2mg/kg/day for a week or 1mg/kg/day for a month);

Fluenz® is **not contraindicated** for use in children or adolescents with stable HIV infection receiving 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, or low-dose immunosuppressive therapy.

In other cases of immunosuppression, the vaccine may be considered – **but this is not in the remit of this PGD**. In such cases, the infant's General Practitioner (GP) should

	<p>issue a Patient Specific Direction (PSD) or administer the vaccine themselves. As with all complex cases, it is good practice to involve the individual's specialist clinician in the decision whether to vaccinate.</p> <p>See <a href="#">Chapter 6</a> of <i>Immunisation Against Infectious Disease: The Green Book</i> for further guidance.</p> <p><b>Temporary Exclusion</b></p> <p>Administration of Fluenz<sup>®</sup> should be postponed in infants and children suffering from heavy nasal congestion. This is because heavy congestion may impede delivery of the vaccine to the nasopharyngeal mucosa;</p> <p>Administration of Fluenz<sup>®</sup> should be postponed in infants children and adolescents with active wheezing at the time of vaccination;</p> <p>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.</p> <p>Otherwise, minor illness without fever or systemic upset is not a contra-indication for immunisation.</p>
<p><b>Action if excluded</b></p>	<p>Where age is the exclusion criteria, no further action will be required.</p> <p><b>All pregnant teenagers should be offered inactivated influenza vaccine.</b></p> <p>Vaccination with inactivated influenza vaccine should be considered in most patients with immunosuppression.</p> <p>Seek appropriate advice from a Consultant in Health Protection or the individual's clinician.</p> <p>Also see section on <a href="#">Precautions</a> below, particularly vaccination of close household contacts.</p> <p><b>Egg allergy</b></p> <p>Individuals with confirmed anaphylaxis to egg can be immunised with an egg-free influenza vaccine if available, or referred to specialists for vaccination in hospital using an inactivated influenza vaccine with ovalbumin content less than 0.12µg/ml.</p> <p>All other egg allergic individuals can be given egg-free vaccine or inactivated influenza vaccine with ovalbumin content less than 0.12µg/ml, administered as recommended, in primary care.</p> <p><b>Temporary exclusion</b></p>

	<p>In case of postponement due to acute illness or heavy nasal congestion, arrange a future date for vaccination (if age inclusion criteria still apply).</p> <p>Document in infant's clinical records.</p> <p>In a GP practice setting, inform or refer to the GP.</p>
<b>Action if patient or carer declines treatment</b>	<p>Advise patient/ parent/ guardian/ carer about the protective effects of the vaccine, the risks of infection and disease, including potential complications.</p> <p>Document advice given and decision reached.</p> <p>In a GP practice setting, inform or refer to the GP.</p>
<b>Reference to national / local policies or guidelines</b>	<p><u>Chapter 19 of Immunisation Against Infectious Disease: The Green Book:</u>  <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147958/Green-Book-Chapter-19-v4_71.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147958/Green-Book-Chapter-19-v4_71.pdf</a></p> <p><u>Joint letter</u> from the Department of Health/ Public Health England/ NHS England 5<sup>th</sup> June 2013:  <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/207008/130613_Flu_Letter_v_29_Gateway_GW_signed.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/207008/130613_Flu_Letter_v_29_Gateway_GW_signed.pdf</a></p> <p><u>Second joint letter</u> from Department of Health and Public Health England/ NHS England 6 July 2013, <i>The flu immunisation programme 2013/14 – extension to children</i> :  <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/225360/Childrens_flu_letter_2013.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/225360/Childrens_flu_letter_2013.pdf</a></p> <p><u>JCVI statement</u> on the annual influenza vaccination programme – extension of the programme to children 25 July 2012:  <a href="http://webarchive.nationalarchives.gov.uk/20130402145952/http://media.dh.gov.uk/network/261/files/2012/07/jcvi-statement-on-the-annual-influenza-vaccination-programme-25-july-2012.pdf">http://webarchive.nationalarchives.gov.uk/20130402145952/http://media.dh.gov.uk/network/261/files/2012/07/jcvi-statement-on-the-annual-influenza-vaccination-programme-25-july-2012.pdf</a></p> <p>Fluenz® <u>Summary of Product Characteristics:</u>  <a href="http://www.medicines.org.uk/emc/medicine/25084">http://www.medicines.org.uk/emc/medicine/25084</a></p>
<b>Precautions</b>	<p>See section on <u>Criteria for exclusion</u>.</p> <p>Individuals who have immunosuppression and HIV infection may not make a full antibody response. Consideration should be given to the influenza vaccination of household contacts of immunocompromised individuals.</p>

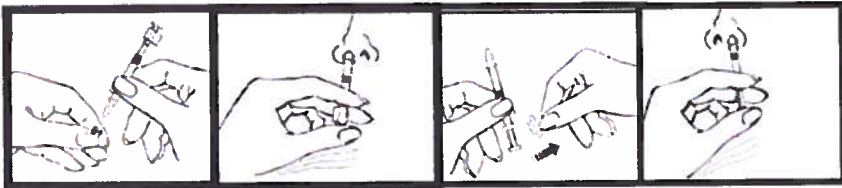
There is a potential for transmission of live attenuated influenza virus in Fluenz® to severely immunocompromised contacts for one to two weeks following vaccination. Where close contact with immunocompromised patients is likely or unavoidable, appropriate alternative inactivated influenza vaccines should be considered.

No data exist regarding the safety of intranasal administration of Fluenz® in children with unrepaired craniofacial malformations.

Please see [Chapter 19](#) of the *Immunisation Against Infectious Disease: The Green Book* for more details.

## 2. Description of Treatment

<b>Name, strength &amp; formulation of drug</b>	Fluenz® <b>nasal spray</b> suspension (0.2 ml) in pre-filled <b>nasal</b> applicator (Influenza vaccine, live). Fluenz® contains cold-adapted, temperature sensitive, attenuated virus strains.
<b>Presentation</b>	Fluenz® vaccine is supplied as a <b>nasal spray</b> suspension, colourless to pale yellow, clear to opalescent. Small white particles may be present. The suspension (0.2ml) is contained in a single-use <b>nasal</b> applicator with a plunger, plunger-stopper, dose-divider clip and protective tip cap.
<b>Storage</b>	Vaccines should be stored in the original packaging at +2°C to +8°C and should be protected from light. All vaccines are sensitive to some extent to heat or cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Effectiveness will be reduced for vaccines unless they have been stored at the correct temperature. 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.
<b>Legal status</b>	Prescription Only Medicine (POM).
<b>Black Triangle▼</b>	Yes.
<b>Unlicensed / off label use</b>	No.
<b>Route / method</b>	<p>Fluenz® vaccine is given intranasally.</p> <p>Fluenz® vaccine must NOT be injected.</p> <p>Instructions for administration of the vaccine: Single application in each nostril of 0.1ml</p> <p>To administer the vaccine, carefully remove the rubber 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.</p> <p>The patient can breathe normally during vaccine administration and there is no need to actively inhale or sniff.</p>

	<p>Fluenz® vaccine is for <b>intranasal application</b> only.</p> <div></div> <table><tr><td>Remove protective tip cap. Do <b>not</b> remove the dose-divider</td><td>With the child upright, position the applicator and depress as rapidly as possible</td><td>Pinch and remove the dose-divider clip from the plunger</td><td>Administer the remaining vaccine into the other nostril</td></tr></table> <p>The Summary of Product Characteristics for Fluenz® provides further guidance on administration. <a href="http://www.medicines.org.uk/emc/medicine/25084">http://www.medicines.org.uk/emc/medicine/25084</a></p>	Remove protective tip cap. Do <b>not</b> remove the dose-divider	With the child upright, position the applicator and depress as rapidly as possible	Pinch and remove the dose-divider clip from the plunger	Administer the remaining vaccine into the other nostril
Remove protective tip cap. Do <b>not</b> remove the dose-divider	With the child upright, position the applicator and depress as rapidly as possible	Pinch and remove the dose-divider clip from the plunger	Administer the remaining vaccine into the other nostril		
Dose	<p><b>Schedule</b></p> <p>First dose of 0.2ml administered as 0.1ml in each nostril of Fluenz® intranasal vaccine:</p> <ul style="list-style-type: none"><li>• Infants aged 2 and 3 years;</li><li>• Children aged 4 to less than 11 years resident/ at school in a pilot area as appropriate;</li><li>• Children aged 4 to 17 years in a clinical risk group category listed in <a href="#">Chapter 19</a> of <i>Immunisation Against Infectious Disease: The Green Book</i>:</li></ul> <p>Second dose of 0.1ml Fluenz® intranasal vaccine:</p> <ul style="list-style-type: none"><li>• Children aged 2 to less than 9 years who are in a clinical risk group category listed in <a href="#">Chapter 19</a> of the <i>Immunisation Against Infectious Disease: The Green Book</i> and who have not received influenza vaccine before, should receive a second dose of Fluenz® at least 4 weeks after the first dose.</li></ul>				
Frequency of administration	See section on <a href="#">Dose</a> .				
Duration of treatment	See section on <a href="#">Dose</a> .				
Supply	See section on <a href="#">Presentation</a> .				
Total doses	<p>Maximum two doses (see section on <a href="#">Dose</a>).</p> <p>Single dose unless child or adolescent is in a risk category.</p>				

<b>Disposal</b>	Equipment used for immunisation, including used vials, ampoules, or partially discharged vaccines in an oral applicator, should be disposed of at the end of a session by sealing in a proper, puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01 (Department of Health, 2006).
<b>Drug Interactions<sup>3</sup></b>	<p>Other live attenuated vaccines, such as MMR, administered as part of the routine childhood immunisation programme can be given at the same time as Fluenz® or after a four week interval. Fluenz® 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 be given. The co-administration of Fluenz® with inactivated vaccines has not been studied but these should be given according to the usual schedule.</p> <p>There is no data on the concurrent use of Fluenz® with antiviral agents active against influenza but these are likely to reduce the effectiveness of Fluenz® if given within 48 hours before or two weeks after vaccination.</p> <p>Children and adolescents younger than 18 years of age: Do not administer Fluenz® if receiving salicylate therapy and do not use salicylates for 4 weeks after vaccination.</p>
<b>Identification &amp; Management of Adverse Reactions<sup>2</sup></b>	<p>The most common adverse reactions observed after administration of Fluenz® are decreased appetite, headache, nasal congestion, rhinorrhoea, malaise. Less common reactions include myalgia and pyrexia and uncommon reactions include epistaxis and rash.</p> <p>A detailed list of adverse reactions associated with Fluenz® is available in the Summary of Product Characteristics for this vaccine, which is available from the European Medicines Agency website: <a href="http://www.medicines.org.uk/emc/medicine/25084">http://www.medicines.org.uk/emc/medicine/25084</a></p>
<b>Patient advice /Follow up treatment</b>	When applicable, advise parent/carers when the subsequent dose is due.
<b>Reporting procedure of Adverse Reactions</b>	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: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a>

<sup>2</sup> Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

	<p>Any serious adverse reaction to the vaccine should also be documented in the patient's record.</p> <p>The patient's GP should also be informed.</p>
<b>Advice to patient/carer including written information</b>	<p>Supply marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Inform patient/carer of possible side effects and their management.</p> <p>The parent/carer should be advised to seek medical advice in the event of a severe adverse reaction.</p> <p>Vaccine recipients should be informed that Fluenz® 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.</p>
<b>Special Considerations/ Additional Information</b>	<p>As with most vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of Fluenz®.</p> <p>Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection and access to a telephone.</p> <p>Minor illnesses without fever or systemic upset are NOT valid reasons to postpone immunisation. 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 signs or symptoms to adverse effects of the vaccine.</p>

<b>Records</b>	<p>Record:</p> <ul style="list-style-type: none"> <li>• That valid informed consent was given</li> <li>• Name of patient, address, date of birth and General Practitioner with whom the patient is registered</li> <li>• Diagnosis</li> <li>• Name of member of staff who supplied the medicine</li> <li>• Date of supply</li> <li>• Dose and form of medicine supplied</li> <li>• Quantity supplied</li> <li>• Batch number and expiry date</li> <li>• Advice given</li> <li>• Advice given if excluded or declines treatment</li> <li>• Record how the patient's central record or GP surgery</li> </ul>
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	<p>record will be updated</p> <ul style="list-style-type: none"> <li>• Details of any Adverse Drug Reactions and actions taken</li> <li>• Record supplied via Patient Group Direction</li> </ul> <p>All records should be clear, legible and contemporaneous</p> <p>The information should be recorded as appropriate in:</p> <p>Patient's General Practitioner record or other patient record, depending on location</p> <p>AND the personal Child Health record (PCHR) – the <i>Red Book</i>.</p> <p>A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.</p> <p>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 25<sup>th</sup> birthday, or for 8 years following a child's death.</p> <p>Data must be stored in accordance with Caldicott guidance and the Data Protection Act.</p>
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### 3. Characteristics of Staff

<b>Qualifications required</b>	<p>Nurses currently registered with the Nursing and Midwifery Council (NMC);</p> <p>Other trained and appropriately qualified professionals as detailed in <a href="#">Chapter 5</a> of <i>Immunisation Against Infectious Disease: The Green Book</i>.</p>
<b>Additional requirements</b>	<p>You must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it;</p> <p>You must have undertaken appropriate training for working under a PGD for supply of medicines;</p> <p>You must have undertaken training appropriate to this PGD;</p> <p>You must be competent to undertake immunisation and vaccination and to discuss issues related to them;</p> <p>You must be competent in the recognition and management of anaphylaxis;</p> <p>You must be competent in the clinical assessment of patients that require post-exposure prophylaxis for influenza.</p>
<b>Continued training requirements</b>	<ul style="list-style-type: none"> <li>You must maintain your own level of updating with evidence of Continued Professional Development (CPD)</li> <li>You should be constantly alert to any subsequent recommendations from the Department of Health and other sources of medicines information</li> </ul>

#### 4. PGD Development

PGD developed and peer reviewed by the following on behalf of Public Health England:

Developed & produced by:	Name	Signature	Date
Senior Pharmacist	Jackie Lamberty	 J LAMBERTY	4 <sup>th</sup> August 2013
Doctor (Lead author)	Dr Penelope Toff		23 <sup>rd</sup> July 2013
Primary Care Practice nurse	Priti Shah		24 <sup>th</sup> July 2013

#### Acknowledgements

Name	Designation
Dr Mary Ramsay	Head of Immunisation, PHE
Dr Nick Phin	Head of Legionella and Influenza Preparedness & Response, PHE
Joanne Yarwood	Head of planning and implementation, Immunisation, PHE
Dr Sally Millership	Consultant in Communicable Disease, PHE

## 5. ORGANISATIONAL AUTHORISATIONS

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met.

Complete details below or use format agreed according to local policy.

Organisation Approvals		DATE
Local Clinical Governance Committee e.g. DTC/MMT SMT 30/8/13	<i>/r DAVID BLAU</i>	29 <sup>th</sup> August 2013
Additional signatories according to local policy e.g. independent contractor providers.	<i>M KITCHING</i>	29/8/2013

Organisations must add an Individual Practitioner Authorisation sheet or List of Authorised Practitioners. This varies according to local policy but this should be a signature list or an individual agreement according to local policy.

**BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT**

**PATIENT GROUP DIRECTIONS DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**

**IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTISE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE**

**Practitioner**

**I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct**

Signed.....Date.....

..

Name  
(Print).....

Designation.....

..

**Authorising Manager**

Manager to give authorisation on behalf of xxx (insert name of organisation) for the named Health Care Professional who has signed the PGD

Signed..... Date.....

Name (Print).....

Designation.....

**Note to Authorising Manager**

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so

You must give this signed PGD to each Authorised Practitioner as it shows their authorisation to use the PGD

