Public Health England

PHE publications gateway number: 2015271

PATIENT GROUP DIRECTION (PGD)

Supply and administration of live attenuated influenza vaccine nasal spray suspension (Fluenz Tetra®▼), OR supply only in well-defined local circumstances, to children and adolescents from 2 years to under 18 years of age in accordance with the national flu immunisation programme for active immunisation against influenza.

This PGD is for the supply and administration, or supply only, of live attenuated influenza vaccine (LAIV) nasal spray suspension (Fluenz Tetra®▼) by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.[1]

Reference no:	LAIV PGD
Version no:	v07.00
Valid from:	01 September 2018
Review date:	01 April 2019
Expiry date:	31 March 2019

Public Health England has developed this PGD template to facilitate the delivery of publicly funded immunisations in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[2]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers.

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

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

[1] This PGD is not relevant to the national community pharmacy seasonal influenza vaccination advanced service which is for adults only.
[2] This includes any relevant amendments to legislation (eg 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details[3]	Date
Final version	New PHE Fluenz PGD	1 September 2013
Final version – revised	Dose section: second dose amended from 0.1ml to 0.2ml	9 September 2013
Version 02.00	PHE Fluenz PGD transferred to new PHE PGD template and updated for 2015/16 flu programme cohorts.	11 August 2015
Version 03.00	PHE Fluenz PGD amended to include FluMist® Quadrivalent presentation and renamed LAIV PGD.	20 October 2015
Version 04.00	PHE LAIV PGD amended to include 2016/17 programme eligible cohorts, with the addition of children of appropriate age for school year 3, and remove references to FluMist® Quadrivalent presentation.	22 June 2016
Version 05.00	PHE LAIV PGD amended to include the 2017/18 influenza programme eligible cohorts, with the addition of children of appropriate age for school year 4, and exclude individuals who have received a dose of influenza vaccine for the current season (unless second dose indicated).	04 July 2017
Version 06.00	PHE LAIV PGD amended to remove requirement to use CHIS	17 August 2017
Version 07.00	PHE LAIV PGD amended to: • include the 2018/19 influenza programme eligible cohorts, with the addition of children of appropriate age for school year 5 • clarify the requirements for the provision of manufacturer's patient information leaflet following supply and administration • include additional healthcare practitioners in Section 3 • include additional information on exposure to LAIV in pregnancy • include additional information on gelatine content • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	08 June 2018

[3] A summary of the changes between superseded versions may be found in more detail by referring to the Change History in the relevant earlier versions of this PGD.

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		21/06/2018
Doctor	Richard Pebody Consultant Medical Epidemiologist, Immunisation and Countermeasures, PHE		21/06/2018
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		21/06/2018

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Steering Group.

Expert Panel

Name	Designation
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Mary Ramsay	Consultant Epidemiologist and Head of Immunisation and Countermeasures, Public Health England
Tushar Shah	Pharmacy Advisor, NHS England London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East
Sharon Webb	Programme Manager/Registered Midwife, NBHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Principal Pharmacist Bristol, North Somerset & South Gloucestershire Clinical Commissioning Group.

2. 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. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England South (South Central) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Authorised for use by the following organisations and/or services: All NHS England South (South Central) directly commissioned immunisation services. In addition, the PGD may be adopted by provider organisations (providing NHS immunisation and vaccination services) working within the South Central geography. Where this occurs, provider organisations should have this PGD signed off by their governance lead prior to use. Provider organisation staff will be expected to follow local policies and procedures.
Limitations to authorisation
None Stated

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director	**Shahed Ahmed**		**24 July 2018**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to england.southcentral-pgd@nhs.net

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be

used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of Staff

Qualifications and professional registration required	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ("The Green Book"), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the "cold chain" • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies.

Clinical condition or situation to which this PGD applies	LAIV is indicated for the active immunisation of children and adolescents from 2 years to under 18 years of age for the prevention of influenza infection, in line with the recommendations given in Chapter 19 of Immunisation Against Infectious Disease: "The Green Book", the Flu Plan and the annual flu letter.
Criteria for inclusion	**This PGD includes vaccination of children and adolescents for whom LAIV is indicated across the 2018/19 national influenza immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer LAIV beyond the groups they are commissioned to immunise.** **1. Children and adolescents in clinical risk groups:** • children and adolescents from 2 years to under 18 years of age who are in a clinical risk group category listed in Chapter 19 of "The Green Book" (see Appendix A) **2. Children eligible for vaccination with LAIV in accordance with national recommendations for 2018/19 including:** • children aged two and three years on 31 August 2018 (ie date of birth between 1 September 2014 and 31 August 2016 inclusive) • children of appropriate age for reception class and school years 1, 2, 3, 4 and 5 (ie four to ten year olds, with a date of birth between 1 September 2008 and 31 August 2014 inclusive) regardless of whether they attend school ○ some children in reception class and school years 1, 2, 3, 4 and 5 might have a date of birth outside of these date ranges (eg if a child has been accelerated or held back a year). It is acceptable to offer and deliver immunisations to these children with their class peers under this PGD • children of primary school year 6 in pilot areas • children and adolescents from 2 years to under 18 years of age who are household contacts of immunocompromised individuals, ie individuals who expect to share living accommodation on most days over the winter and therefore for whom continuing close contact is unavoidable (Note: contacts of very severely immunocompromised individuals should receive inactivated influenza vaccine and not LAIV, see exclusion criteria)
Criteria for exclusion[4] (continued over page)	LAIV must not be given under this PGD to: • individuals for whom no valid consent has been received (see DH Reference guide to consent for examination or treatment) • children and infants under 2 years of age • adults aged 18 years and over • individuals who have received a dose of influenza vaccine for the current season, unless they are individuals aged 2 to less than 9 years in a clinical risk group category listed in Chapter 19 of the "The Green Book" who should, in the first season they are

[4] 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

Criteria for exclusion (continued)	vaccinated against influenza, receive a second dose of LAIV at least 4 weeks after the first dose • individuals with a confirmed anaphylactic reaction to a previous dose of influenza vaccine • individuals with a confirmed anaphylactic reaction to any component of LAIV (eg gelatine) or residue from the manufacturing process (eg gentamicin), except egg proteins (see Additional information section) • individuals with severe anaphylaxis to egg which has previously required intensive care • individuals with severe asthma, for example children who have taken oral steroids in the past 14 days or are currently taking a high dose of an inhaled steroid, budesonide >800 micrograms/day or equivalent (eg fluticasone >500 micrograms/day) • individuals receiving salicylate therapy (other than topical treatment for localised conditions) because of the association of Reye's syndrome with salicylates and wild-type influenza infection • individuals with unrepaired craniofacial malformations • pregnant individuals, see Action to be taken if the patient is excluded below Note: There is no need to specifically test eligible girls for pregnancy or to advise avoidance of pregnancy in those who have been recently vaccinated. • individuals who are clinically severely immunodeficient due to a condition or immunosuppressive therapy such as: ○ acute and chronic leukaemias ○ lymphoma ○ HIV infection not on highly active antiretroviral therapy (HAART) ○ cellular immune deficiencies ○ high dose corticosteroids (prednisolone at least 2mg/kg/day for a week or 1mg/kg/day for a month or equivalent) see Action to be taken if the patient is excluded below • individuals for whom close contact with very severely immunocompromised patients (eg bone marrow transplant patients requiring isolation) is likely or unavoidable (for example, household members). However, appropriate alternative inactivated influenza vaccines should be considered. **Temporary exclusion** LAIV administration should be postponed for individuals who: • are suffering from acute febrile illness until completely recovered • are suffering from heavy nasal congestion which may impede delivery of the vaccine to the nasopharyngeal mucosa until congestion has resolved • have suffered wheezing in the past 72 hours or those who have increased their use of bronchodilators in the previous 72 hours, see Action to be taken if the patient is excluded below • received treatment with influenza antiviral agents in the last 48 hours until 48 hours following the cessation of treatment with influenza antiviral agents

Continued over page

Cautions including any relevant action to be taken	Individuals who have immunosuppression and HIV infection may not make a full antibody response to the vaccine. Consideration should be given to the influenza vaccination of household contacts of immunocompromised individuals. There is a theoretical potential for transmission of live attenuated influenza virus to immunocompromised contacts for one to two weeks following vaccination. Where close contact with very severely immunocompromised patients is likely or unavoidable, appropriate alternative inactivated influenza vaccines should be considered.
Action to be taken if the patient is excluded	Where individuals are excluded and are in a routine cohort with no clinical risk factors, no further action will be required. Children and adolescents with clinical risk factors who are excluded from receiving LAIV should be considered for an appropriate alternative inactivated influenza vaccine. Children and adolescents with a history of severe anaphylaxis to egg which has required intensive care, and who require protection against influenza because they are in a clinical risk group, should be referred to specialists for immunisation in hospital. JCVI has advised that, except for those with severe anaphylaxis to egg which has previously required intensive care, children with an egg allergy can be safely vaccinated with LAIV in any setting (including primary care and schools). Individuals with severe asthma should only be given LAIV on the advice of their specialist (and under a PSD). As these children are a defined risk group for influenza, those who cannot receive LAIV should receive an inactivated influenza vaccine. All pregnant individuals should be offered inactivated influenza vaccine unless otherwise contraindicated. Vaccination with inactivated influenza vaccine should be considered for immunosuppressed individuals excluded from receiving LAIV and those who are contacts of individuals who are very severely immunocompromised. Individuals temporarily excluded may be offered LAIV at a later date. In case of postponement arrange a future date for vaccination. Individuals who have suffered wheezing in the past 72 hours or those who have increased their use of bronchodilators in the previous 72 hours whose condition has not improved after a further 72 hours should be offered an inactivated influenza vaccine to avoid delaying protection in this high risk group. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.

Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the individual's behalf, must be obtained for each administration. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and decision reached. In a GP practice setting, inform or refer to the GP or prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of Treatment

<table>
<tr><td>Name, strength & formulation of drug</td><td>Live attenuated influenza vaccine nasal spray suspension (0.2 ml) (Influenza vaccine, live attenuated) eg:
Fluenz Tetra®▼ nasal spray suspension (0.2 ml) in pre-filled nasal applicator (influenza vaccine, live attenuated)</td></tr>
<tr><td>Legal category</td><td>Prescription only medicine (POM)</td></tr>
<tr><td>Black triangle▼</td><td>Yes</td></tr>
<tr><td>Off-label use</td><td>Fluenz Tetra®▼ SPC states “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.” However, JCVI has advised that for children who are not in a clinical risk group, only require a single dose of LAIV irrespective of whether they have received influenza vaccine previously.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</td></tr>
<tr><td>Route / method of administration</td><td>Administration under this PGD must be directly by the registered health professional named in section 7.

If the PGD is used for “supply only”, subsequent self-administration or administration by another healthcare worker is outside the remit of this PGD and should only take place in well-defined local circumstances covered by protocols and training.

LAIV is given intranasally.

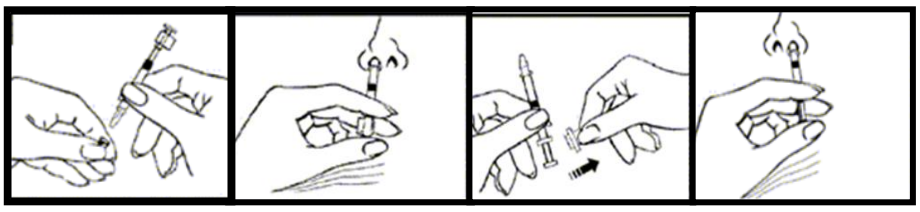
LAIV must NOT be injected.

Instructions for administration of the vaccine by the registered practitioner:

Single application in each nostril of 0.1ml.

The individual can breathe normally during vaccine administration and there is no need to actively inhale or sniff.

LAIV is for intranasal application only.

 
<table><tr><td>Remove protective tip cap.
Do not remove the dose-divider</td><td>With the patient 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>
The Summary of Product Characteristics for Fluenz Tetra®▼ provides further guidance on administration.
http://www.medicines.org.uk/emc/medicine/29112</td></tr>
</table>

Dose and frequency of administration	Single dose of 0.2ml of LAIV administered as 0.1ml in each nostril. **Children in clinical risk groups** Children aged 2 to less than 9 years who are in a clinical risk group category listed in Chapter 19 of the "The Green Book" and who have not received influenza vaccine before, should receive a second dose of LAIV at least 4 weeks after the first dose. Second dose of 0.2ml of LAIV administered as 0.1ml in each nostril.
Duration of treatment	See section on Dose.
Quantity to be supplied / administered	0.2ml dose to be administered as 0.1ml in each nostril. OR 0.2ml of LAIV to be supplied to the individual for immediate self-administration or administration by an appropriately trained healthcare support worker (HCSW) within the clinic setting. Note: The act of administration by anyone other than the registered professional named in Section 7 is outside the remit of this PGD and should only take place in well-defined local circumstances covered by protocols and training. **Children aged 2 years to less than 9 years old in a clinical risk category and receiving influenza immunisation for the first time** This dose (0.2ml) should be repeated after a 4 week interval.
Supplies	LAIV has been purchased centrally for children in the annual routine cohorts and for children aged 2 years to under 18 years of age in clinical risk groups. These vaccines should be ordered as per the usual mechanisms for the routine childhood immunisation programme. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Before use, the vaccine may be removed from the cold-chain, 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.
Disposal	Equipment used for immunisation, including discharged or partially discharged vaccines in an applicator, should be disposed of at the end of a session, as medicinally-contaminated clinical waste for incineration, in a yellow UN-approved waste receptacle (this is usually a sharps box), according to local authority regulations and guidance in the technical memorandum 07-01 (Department of Health, 2013).
Drug interactions (continued over page)	There is a potential for influenza antiviral agents to lower the effectiveness of the LAIV. Therefore, influenza antiviral agents and LAIV should not be administered concomitantly. LAIV should be delayed until 48 hours following the cessation of treatment with influenza antiviral agents. Administration of influenza antiviral agents within the two weeks

Drug interactions (continued)	following administration of LAIV may adversely affect the effectiveness of the vaccine. Children and adolescents younger than 18 years of age: Do not administer LAIV if receiving salicylate therapy (other than topical treatment for localised conditions) and do not use salicylates for 4 weeks after vaccination. LAIV can be given at the same time as other live or inactivated vaccines. Although it was previously recommended that, where vaccines cannot be administered simultaneously, a four-week interval should be observed between live viral vaccines, JCVI have advised that no specific intervals need to be observed between LAIV and other live vaccines (see PHE revised recommendations for administering more than one live vaccine). A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification and management of adverse reactions	The most common adverse reactions observed after administration of LAIV are decreased appetite, headache, nasal congestion, rhinorrhoea, malaise. Less common reactions include myalgia and pyrexia and uncommon reactions include hypersensitivity reactions, epistaxis and rash. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of adverse reactions	As Fluenz Tetra® ▼ is a black triangle product, any suspected adverse reactions should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Manufacturer's packaging is required to include a patient information leaflet (PIL) which should accompany the supply of vaccine under this PGD. When LAIV is administered there is no legal requirement to provide the manufacturer's PIL to the individual at the time of administration, although this may be considered good practice.
Patient advice / follow up treatment (continued over page)	Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of a severe adverse reaction. When applicable, advise the individual/parent/carer when the subsequent dose is due. Vaccine recipients should be informed that LAIV has the theoretical potential for transmission to immunocompromised contacts. Vaccine recipients should attempt to avoid, whenever possible, close association with very severely immunocompromised individuals (eg bone marrow transplant recipients requiring isolation) for 1-2 weeks following vaccination.

Patient advice / follow up treatment (continued)	If the PGD is used for supply only, advise the individual/parent/carer of the process they need to follow for subsequent administration eg refer immediately to appropriately trained HCSW within the clinic setting. When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations / additional information (continued over page)	As with most vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of LAIV. Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. For children under the age of 16 years, those assessed as Gillick competent can self-consent (see DH Reference guide to consent for examination or treatment). 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. LAIV contains a highly processed form of gelatine (derived from pigs). Some faith groups do not accept the use of porcine gelatine in medical products. Only those who are in clinical risk groups are able to receive an inactivated injectable vaccine as an alternative (see PHE IM Influenza PGD). JCVI has advised that, except for those with severe anaphylaxis to egg which has previously required intensive care, children with an egg allergy can be safely vaccinated with LAIV in any setting (including primary care and schools). Individuals on high dose inhaled corticosteroids are excluded from this PGD, due to the severity of their respiratory disease, and LAIV should only be given on the advice of their specialist. Individuals on high dose inhaled corticosteroids are not excluded for reasons of immunosuppression. LAIV is not contraindicated for use in children or adolescents with stable HIV infection receiving antiretroviral therapy; or who are receiving topical corticosteroids, standard dose inhaled corticosteroids, low-dose systemic corticosteroids or those receiving corticosteroids as replacement therapy, eg for adrenal insufficiency or low-dose immunosuppressive therapy. This PGD may be used for these individuals. In more than 300 case reports in the AstraZeneca safety database of vaccine administration to pregnant women, no unusual patterns of pregnancy complications or foetal outcomes were observed. While animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity, and post-marketing data offer some reassurance in the event of inadvertent administration of the vaccine, LAIV is not recommended during pregnancy. Inactivated influenza vaccine should be offered to pregnant individuals (see PHE IM Influenza PGD). If the PGD is used for supply only for subsequent administration by an appropriately trained HCSW, the registered practitioner named in Section 7 of this PGD must supply the vaccine to the individual/carer.

Special considerations / additional information (continued)	The HCSW cannot supply the medicine. **Exposure of healthcare professionals** Very severely immunosuppressed individuals should not administer LAIV. Other healthcare workers who have less severe immunosuppression or are pregnant, should follow normal clinical practice to avoid inhaling the vaccine and ensure that they themselves are appropriately vaccinated.
Records	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • clinical risk group indication for immunisation if applicable • name of immuniser • name and brand of vaccine • date of administration or supply • dose, form and route of administration of vaccine • quantity administered or supplied • batch number and expiry date • advice given; including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • whether supplied only or supplied and administered via Patient Group Direction (PGD). Records should be signed and dated (or password controlled immunisers record on e-records). All records should be clear, legible and contemporaneous. It is important that vaccinations given either at a general practice or elsewhere (for example, at schools or community pharmacies) are recorded on appropriate health records for the individual (using the appropriate clinical code). If given elsewhere, a record of vaccination should be returned to the individual's general practice to ensure a complete health record is held by the GP, allow clinical follow up and to avoid duplicate vaccination. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key References

Key references	**LAIV** • Immunisation Against Infectious Disease: The Green Book. Chapter 19, Updated 1 December 2017. https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19 • Collection: Annual Flu Programme. Updated 26 March 2018 https://www.gov.uk/government/collections/annual-flu-programme • The national flu immunisation programme 2018 to 2019: supporting letter. Published 26 March 2018. https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan • Summary of Product Characteristics for Fluenz Tetra®▼. AstraZeneca UK Ltd. 27 March 2018 http://www.medicines.org.uk/emc/medicine/29112 • Revised recommendations for administering more than 1 live vaccine. 24 April 2015. https://www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. https://www.nice.org.uk/guidance/mpg2/resources • PHE Immunisation Collection. https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines • Reference guide to consent for examination or treatment, Department of Health, published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

7. Practitioner authorisation sheet

LAIV PGD v07.00 Valid from: 01/09/2018 Expiry: 31/03/2019

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

Practitioner

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 and professional code of conduct.

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.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of NHS England South (South Central) for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

APPENDIX A

Clinical risk groups who should receive an influenza immunisation

Influenza vaccine should be offered to people in the clinical risk categories set out below.

Clinical risk category	Examples (this list is not exhaustive and decisions should be based on clinical judgement)
Chronic respiratory disease	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children who have previously been admitted to hospital for lower respiratory tract disease.
Chronic heart disease	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
Chronic kidney disease	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease	Cirrhosis, biliary atresia, chronic hepatitis.
Chronic neurological disease (included in the DES directions for Wales)	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (eg polio syndrome sufferers). Clinicians should offer immunisation, based on individual assessment, to clinically vulnerable individuals including those with cerebral palsy, learning disabilities, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability.
Diabetes	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes.
Immunosuppression ***(see contraindications and precautions section on live attenuated influenza vaccine)***	Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (eg IRAK-4, NEMO, complement disorder). Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kg, a dose of 1mg or more per kg per day. It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immunocompromised patients may have a suboptimal immunological response to the vaccine.
Asplenia or dysfunction of the spleen	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Pregnant women	Pregnant women at any stage of pregnancy (first, second or third trimesters).
Morbid obesity (class III obesity)	Adults with a Body Mass Index ≥ 40 kg/m².