Public Health England

PHE publications gateway number: GW-498

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:	v08.00
Valid from:	1 September 2019
Review date:	1 April 2020
Expiry date:	31 March 2020

Public Health England has developed this PGD 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-patient-group-direction-pgd

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 (such as 2013 No.235, 2015 No.178 and 2015 No.323).

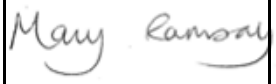
Change history

Version number	Change details[3]	Date
Final version	New PHE Fluenz PGD	1 September 2013
Final version – revised	See earlier version of this PGD for change details.	9 September 2013
V02.00	See earlier version of this PGD for change details.	11 August 2015
V03.00	See earlier version of this PGD for change details.	20 October 2015
V04.00	See earlier version of this PGD for change details.	22 June 2016
V05.00	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
V06.00	PHE LAIV PGD amended to remove requirement to use CHIS	17 August 2017
V07.00	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
V08.00	PHE LAIV PGD amended to: • include the 2019/20 influenza programme eligible cohorts, with the addition of children of appropriate age for school year 6 • remove the exclusion of individuals on high dose inhaled corticosteroids and replace with the exclusion of individuals who require oral steroid for the maintenance of asthma control or have previously required intensive care for an asthma exacerbation, in accordance with updated recommendations from JCVI and in Chapter 19 of 'The Green Book' • include reference to the Directed Enhanced Service and offer to morbidly obese adults from 16 years of age • include minor rewording, layout and formatting changes to remove duplication and for clarity and consistency with other PHE PGD templates	8 May 2019

[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 and Countermeasures, PHE		05/06/2019
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		04/06/2019
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		24/05/2019

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 Delivery Board.

Expert Panel

Name	Designation
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
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 and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement North West (Lancashire and South Cumbria Screening and immunisation Team)
Lesley McFarlane	Screening and Immunisation Co-ordinator, Public Health England / NHS England and NHS Improvement Midlands (Leicestershire, Lincolnshire and Northamptonshire)
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Richard Pebody	Consultant Medical Epidemiologist, Immunisation and Countermeasures, Public Health England
Tushar Shah	Pharmacy Advisor, NHS England and NHS Improvement London Region
Sharon Webb	Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England

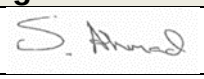
1. Organisational authorisations

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 HAMPSHIRE AND THAMES VALLEY (HTV) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England HTV directly commissioned immunisation services. In addition, the PGD may be adopted by provider organisations (providing NHS immunisation and vaccination services) working within the HTV 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. For instance, all NHS England commissioned immunisation services or NHS Trust providing immunisation services.
Limitations to authorisation
None stated.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director	**Shahed Ahmad**		**29/7/19**

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.

2. 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.

3. 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' and the annual flu letter.
Criteria for inclusion	Individuals eligible for vaccination with LAIV in accordance with national recommendations for 2019/20 including: • 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) • children aged 2 and 3 years on 31 August 2019 (with a date of birth between 1 September 2015 and 31 August 2017 inclusive) • children of appropriate age for reception class and school years 1, 2, 3, 4, 5 and 6 (that is 4 to 11 year olds, with a date of birth between 1 September 2008 and 31 August 2015 inclusive) regardless of whether they attend school ○ some children in reception class and school years 1, 2, 3, 4, 5 and 6 might have a date of birth outside of these date ranges (for instance if a child has been accelerated or held back a year), it is acceptable to offer and provide immunisations to these children with their class peers under this PGD • children and adolescents from 2 years to under 18 years of age who are household contacts of immunocompromised individuals, such as 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 Inactivated Influenza PGD)
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 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 (such as gelatine) or residue from the manufacturing process (such as gentamicin), with the exception of egg proteins (see Additional information section) • individuals with severe anaphylaxis to egg which has previously required intensive care • individuals with severe asthma who have previously required

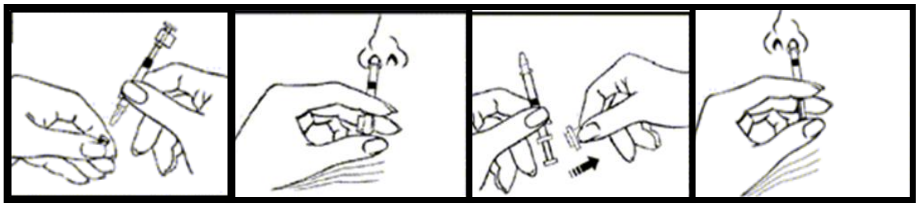
[4] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

Criteria for exclusion (continued)	intensive care for asthma exacerbation or who require regular oral steroids for the maintenance of asthma control, for example children who are currently taking oral steroids or who have been prescribed oral steroids in the past 14 days, unless LAIV is advised by their respiratory specialist • 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 the PHE Inactivated Influenza PGD 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 the PHE Inactivated Influenza PGD • individuals for whom close contact with very severely immunocompromised patients (for instance, bone marrow transplant patients requiring isolation) is likely or unavoidable (for example, household members), see the PHE Inactivated Influenza PGD **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 a history of active 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 • received treatment with influenza antiviral agents in the last 48 hours until 48 hours following the cessation of treatment with influenza antiviral agents
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.
Action to be taken if the patient is excluded Continued over page	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, see the PHE Inactivated Influenza PGD. 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

Action to be taken if the patient is excluded (continued)	to specialists for immunisation in hospital. LAIV remains the preferred vaccine for this group and the intranasal route is less likely to cause systemic reactions. 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 who have previously required intensive care for asthma exacerbation or who require regular oral steroids for the maintenance of asthma control 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, see the PHE Inactivated Influenza PGD. All pregnant individuals should be offered inactivated influenza vaccine unless otherwise contraindicated, see the PHE Inactivated Influenza PGD. 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, see the PHE Inactivated Influenza PGD. Individuals temporarily excluded may be offered LAIV at a later date. In case of postponement arrange a future date for vaccination. Individuals who have a history of active 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, see the PHE Inactivated Influenza PGD. 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 the 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

4. Description of Treatment

Name, strength & formulation of drug	Live attenuated influenza vaccine nasal spray suspension (0.2 ml) (Influenza vaccine, live attenuated), for instance: • Fluenz Tetra nasal spray suspension (0.2 ml) in pre-filled nasal applicator (influenza vaccine, live attenuated)
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	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 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. Fluenz Tetra is contraindicated in children and adolescents receiving salicylate therapy because of the association of Reye's syndrome with salicylates and wild-type influenza infection. However, LAIV may be administered off-label to individuals receiving topical salicylate treatment for the management of localised conditions, in accordance with Chapter 19 of the 'The Green Book'. 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). Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. 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.
Route / method of administration Continued over page	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. Administration under this PGD must be directly by the registered health professional named in section 7. LAIV is for intranasal application only. 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.

<table>
<tr><td>Route / method of administration
(continued)</td><td>Instructions for administration
 
<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 SPC provides further guidance on administration:
http://www.medicines.org.uk/emc/medicine/29112</td></tr>
<tr><td>Dose and frequency of administration</td><td>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.</td></tr>
<tr><td>Duration of treatment</td><td>See section on Dose.</td></tr>
<tr><td>Quantity to be supplied / administered</td><td>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. Vaccine supplies which are not legally over-labelled for individual use must be administered prior to the individual leaving the immunisation session. 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.</td></tr>
<tr><td>Supplies</td><td>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 Green Book Chapter 3).</td></tr>
<tr><td>Storage

Continued over page</td><td>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</td></tr>
</table>

Storage (continued)	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. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance.
Disposal	Equipment used for immunisation, including discharged or partially discharged vaccines in an applicator, should be disposed of safely, 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	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 2 weeks 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 4-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. 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	Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Any 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	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. The individual/parent/carer 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 (such as bone marrow transplant recipients requiring isolation) for 1-2 weeks following vaccination. If the PGD is used for supply only, advise the individual/parent/carer of the process they need to follow for subsequent administration, for instance refer them immediately to an 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 influenza vaccine as an alternative (see the PHE Inactivated 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). LAIV is not contraindicated for use in children or adolescents with stable HIV infection receiving antiretroviral therapy; or who are receiving topical corticosteroids, inhaled corticosteroids, low-dose

Special considerations / additional information (continued)	systemic corticosteroids or those receiving corticosteroids as replacement therapy (such as 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 the PHE Inactivated Influenza PGD). In accordance with Appendix A and the Seasonal Influenza Directed Enhanced Service, morbidly obese adults (aged from 16 years) with a BMI > 40kg/m^2 should be offered influenza immunisation. Individuals with learning disabilities may require reasonable adjustments to support vaccination (see https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities). A PSD may be required. 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. 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 Continued over page	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 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

Records (continued)	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 23 April 2019. https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19 • Collection: Annual Flu Programme. Updated 22 March 2019. https://www.gov.uk/government/collections/annual-flu-programme • The national flu immunisation programme 2019 to 2020: supporting letter. Published 22 March 2019. https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan • GP Contract 2019/20: NHS England Enhanced Service Specifications. https://www.england.nhs.uk/publication/gp-contract-2019-20-nhs-england-enhanced-service-specifications/ • Summary of Product Characteristics for Fluenz Tetra. AstraZeneca UK Ltd. 28 January 2019. http://www.medicines.org.uk/emc/medicine/29112 • PHE Inactivated Influenza Vaccine PGD. https://www.gov.uk/government/publications/intramuscular-inactivated-influenza-vaccine-patient-group-direction-pgd-template • Flu Vaccinations: Supporting people with learning disabilities. Updated 25 September 2018. https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities **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. Updated March 2017. 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 • 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 v08.00 Valid from: 01/09/2019 Expiry: 31/03/2020

Before signing this PGD, check that the document has had the necessary authorisations in section 2. 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 HTV** 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 (e.g. 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 (e.g. 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.