Public Health England

PHE publications gateway number: GOV-9225

Live attenuated influenza vaccine nasal spray suspension (LAIV) Patient Group Direction (PGD)

This PGD is for the supply and administration, or supply only, of live attenuated influenza vaccine (LAIV) nasal spray suspension (Fluenz Tetra) to children and adolescents from 2 years to under 18 years of age in accordance with the national flu immunisation programme.

This PGD is for the supply and administration, or supply only, of LAIV 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:	v10.00
Valid from:	1 September 2021
Review date:	1 April 2022
Expiry date:	31 March 2022

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. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.wmid-imms@nhs.net

[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	See earlier version of this PGD for change details.	04 July 2017
V06.00	See earlier version of this PGD for change details.	17 August 2017
V07.00	See earlier version of this PGD for change details.	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
V09.00	PHE LAIV PGD amended to: • extend the characteristics of staff to include all registered practitioners legally able to work under PGD • include the 2020/21 influenza programme eligible DOB cohorts and household contacts of those on the Covid-19 Shielded Patient List • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	16 July 2020
V10.00	PHE LAIV PGD amended to: • include the 2020/21 influenza programme eligible cohorts	28 July 2021

[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		30/07/2021
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		30/07/2021
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		30/07/2021

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 Governance Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, Public Health England
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset and 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 (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Principal Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), Public Health England / NHS England and NHS Improvement (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)
Conall Watson	Consultant Epidemiologist, Immunisation and Countermeasures, PHE

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 – West Midlands authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Primary Care services and all organisations commissioned to, or contracted by, NHS England and NHS Improvement – West Midlands to provide immunisation services across the West Midlands area. West Midlands Area covers; Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Shropshire, Solihull, Staffordshire, Walsall, Warwickshire, Wolverhampton and Worcestershire.
Limitations to authorisation
N/A

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director Primary Care & Public Health Commissioning	Trish Thompson		04.08.21

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

Local enquiries regarding the use of this PGD may be directed to england.wmid-imms@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	Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): • 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 the national community pharmacy seasonal influenza vaccination advanced service nor privately provided community pharmacy services) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council. Practitioners must also fulfil all the Additional requirements. Check Section 2 Limitations to authorisation to confirm whether all the registered 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. For further information on immunisation training during the COVID-19 pandemic see Guidance on immunisation training during the COVID-19 pandemic • 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 NHS Improvement 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' and annual flu letter(s).

Criteria for inclusion	Individuals eligible for vaccination with LAIV in accordance with national recommendations for 2021/22 including:
	• all children aged 2 to 15 (but not 16 years or older) on 31 August 2021
	  ○ all those aged 2 and 3 years on 31 August 2021 (with a date of birth on or after 1 September 2017 and on or before 31 August 2019)
	  ○ all primary school-aged children in Reception Year to Year 6 (aged 4 to 10 years old on 31 August 2021) regardless of whether they attend school
	  ○ all secondary school-aged children in Years 7 to Year 11 (aged 11 to 15 years old on 31 August 2021) regardless of whether they attend school
	  some school aged children might be outside of the age ranges outlined in the above paragraphs (for example, 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 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' such as:
	  ○ chronic (long-term) respiratory disease, such as asthma (that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission), chronic obstructive pulmonary disease (COPD) or bronchitis
	  ○ chronic heart disease, such as heart failure
	  ○ chronic kidney disease at stage 3, 4 or 5
	  ○ chronic liver disease
	  ○ chronic neurological disease, such as Parkinson's disease or motor neurone disease
	  ○ learning disability
	  ○ diabetes
	  ○ asplenia or splenic dysfunction
	  ○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)
	  ○ morbidly obese adults (aged from 16 years) with a BMI ≥ 40kg/m^2
	• children and adolescents from 2 years to under 18 years of age who are close 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).
	• individuals, from 16 years to under 18 years of age, who are in receipt of a carer's allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill
	• health and social care staff, from 16 years to under 18 years of age, employed by a registered residential care or nursing home or

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Criteria for inclusion (continued)	registered domiciliary care provider, who are directly involved in the care of vulnerable patients or clients who are at increased risk from exposure to influenza • health and care staff, from 16 years to under 18 years of age, employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable patients or clients who are at increased risk from exposure to influenza • health and social care workers, from 16 years to under 18 years of age, employed through Direct Payments (personal budgets) and/or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to patients and service users.
Criteria for exclusion[4]	LAIV must not be given under this PGD to: • individuals for whom no valid consent has been received (see Chapter 2 of 'The Green Book') • 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 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: o acute and chronic leukaemias o lymphoma o HIV infection not on highly active antiretroviral therapy (HAART) o cellular immune deficiencies o 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

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[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)	• 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 • individuals offered vaccination as part of an employer's occupational health scheme **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.
Action to be taken if the patient is excluded	Children and adolescents who are eligible for influenza vaccination but for whom LAIV is contraindicated (or is otherwise unsuitable, for instance due to the route or non-acceptance of porcine gelatine content) 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 should be referred 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. Egg-allergic adults and children over age two years with egg allergy can alternatively be given the quadrivalent inactivated egg-free vaccine, Flucelvax® Tetra▼, which is licensed for use in this age group (see 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). 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. This PGD covers NHS commissioned services. This PGD does not cover the provision of occupational health schemes or peer-to-peer influenza immunisation (See NHS Specialist Pharmacy Service 'Written instruction

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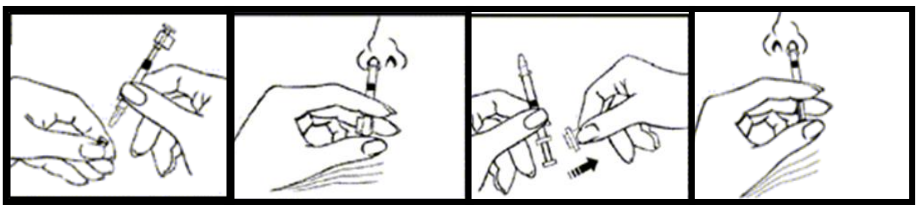
Action to be taken if the patient is excluded (continued)	template for the administration of inactivated seasonal influenza vaccine as part of an occupational health scheme, which may include peer-to-peer immunisation' or the National protocol for inactivated influenza vaccine). Individuals temporarily 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. 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. If the parent of an eligible child refuses LAIV because of its porcine gelatine content (and they understand that it is the most effective product in the programme), advise the individual/parent/carer that they can request an alternative injectable vaccine. PHE has procured QIVc for these children. Refer to PHE Inactivated Influenza Vaccine PGD. Document the advice given and decision reached. Inform or refer to the GP or prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of Treatment

Name, strength and 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 person is outside the remit of this PGD and should only take place in well-defined local circumstances covered by training and local operating protocols. 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. The SPC provides further guidance on administration: http://www.medicines.org.uk/emc/medicine/29112

<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></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 another person 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 training and local operating protocols.
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. 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 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</td></tr>
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Storage (continued)	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. Do not administer LAIV to those 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 when 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 easy 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. 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 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. 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.

Special considerations / additional information (continued)	**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 (or record where an individual is not registered with a GP and that appropriate advice has been given) • 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 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 29 October 2020. https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19 • Collection: Annual Flu Programme. Updated 29 July 2021 https://www.gov.uk/government/collections/annual-flu-programme • The national flu immunisation programme 2021 to 2022: supporting letter. Published 17 July 2021. https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan • GP Contract 2021/22: NHS England and NHS Improvement. https://www.england.nhs.uk/gp/investment/gp-contract/ • Summary of Product Characteristics for Fluenz Tetra. AstraZeneca UK Ltd. 8 March 2021. https://www.medicines.org.uk/emc/product/3296 • 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. 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 • Immunisation Against Infectious Disease: The Green Book. Chapter 2. Updated 18 June 2021. https://www.gov.uk/government/publications/consent-the-green-book-chapter-2 • 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. March 2017. https://www.nice.org.uk/guidance/mpg2/resources • Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them • PHE Guidance on immunisation training during the COVID-19 pandemic. 26 June 2020.

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Key references (continued)	https://www.gov.uk/government/publications/immunisation-training-guidance-during-the-covid-19-pandemic/guidance-on-immunisation-training-during-the-covid-19-pandemic • 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

7. Practitioner authorisation sheet

LAIV PGD v10.00 Valid from: 01/09/2021 Expiry: 31/03/2022

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 PGD you are indicating that you agree to its contents and that you will work within it.

PGDs 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 PGD 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 insert name of organisation 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.

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