UK Health Security Agency

Publications gateway number: GOV-16524

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 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.

Reference no:	LAIV PGD
Version no:	v14.00
Valid from:	1 September 2024
Expiry date:	1 April 2025

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly-funded immunisations in England 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)[1]. **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).

Sections 2 and 7 can be amended within the designated editable fields provide, but only for the purposes for which these sections are provided, namely the responsibilities and governance of the NHS organisations using the PGD. The fields in sections 2 and 7 cannot be used to alter, amend or add to the clinical contents. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.

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 UKHSA PGD templates for authorisation can be found from:
Immunisation patient group direction (PGD) templates

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

[1] This includes any relevant amendments to legislation.

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Vaccination Team, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

Change history

Version number	Change details	Date
v1.00 to v10.00	See earlier version of this PGD for change details.	1 September 2013 to 28 July 2021
v11.00	LAIV PGD amended to: • include the 2022 to 2023 influenza vaccination programme eligible cohorts • update organisation from PHE to the UKHSA	9 August 2022
v12.00	LAIV PGD amended to: • update to include the 2023 to 2024 influenza vaccination programme eligible cohorts • align the very severely immunocompromised statement to Green Book in the inclusion criteria • add children aged 2 years to less than 9 years who are household contacts of immunocompromised individuals in dose section • add additional information about use of the nasal spray in the route and administration section • update the owner of the technical memorandum from Department of Health to NHSE in the disposal section • move headache to less common adverse reaction in line with the SPC in identification of adverse reactions • add use of salicylate caution in patient advice section • add how to obtain accessible information in the written information given to patient section • updated the references	29 June 2023
v13.00	LAIV PGD amended to: • add secondary school Years 7 to 11 to criteria for inclusion section	4 July 2023
v14.00	LAIV PGD amended to: • reflect the change in LAIV vaccine from a quadrivalent to trivalent formulation, in line with recommendations from the World Health Organisation for influenza vaccine composition for use in the northern hemisphere • include information on timing of doses for the 2024 to 2025 season • confirm low ovalbumin content of Fluenz® trivalent • detail appropriate action to take when presented with individuals with unrepaired craniofacial malformations • outline updated storage data: the vaccine may only be removed from the cold chain once, for a maximum period of 12 hours at temperatures between 8°C and 25°C • remove use of oral corticosteroids in the last 14 days for asthma exacerbations as an exclusion, in line with Chapter 19 • removal of advice to reserve inactivated influenza vaccine for individuals who have not shown improvement after a further 72 hours following an initial 72 hour period of active wheeze, increased bronchodilator use, or both • include minor rewording, layout and formatting changes for consistency with other UKHSA PGDs	9 July 2024

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		3 July 2024
Doctor	Jamie Lopez-Bernal Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		3 July 2024
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		3 July 2024

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Committee.

Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Specialist Pharmacist - Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Primary Care Based, Southbourne Surgery
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Elizabeth Luckett	Senior Screening & Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London

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.

NHSE - Midlands uthorises 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/or all organisations commissioned or contracted by NHS England – Midlands to provide immunisation services in: • Derby and Derbyshire • Lincolnshire • Leicester, Leicestershire, and Rutland • Northamptonshire • Nottingham and Nottinghamshire • Herefordshire and Worcestershire • Birmingham and Solihull • Staffordshire and Stoke-on-Trent • Shropshire, Telford, and Wrekin • Black Country • Coventry and Warwickshire.
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Regional Director of Commissioning Integration – NHS England - Midlands	Roz Lindridge		17/07/2024

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

Local enquiries regarding the use of this PGD may be directed to Vaccination Team, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

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	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, see Flu immunisation training recommendations • 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 the UKHSA, NHS England (NHSE) 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, annual flu letter(s) and subsequent correspondence and publications from UKHSA and NHSE.

Criteria for inclusion	For the 2024 to 2025 influenza season, LAIV should be offered in accordance with national recommendations to the following groups:
	
	From 1 September 2024:
	• all those aged 2 or 3 years on 31 August 2024 (with a date of birth on or after 1 September 2020 and on or before 31 August 2022)
	• all primary school-aged children in Reception to Year 6 (aged 4 to 10 years old on 31 August 2024) including home-schooled and other children not in mainstream education
	  ○ 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 influenza immunisation to these children with their class peers under this PGD
	• secondary school-aged children in Years 7 to 11 including home-schooled and other children not in mainstream education
	• 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, but see also criteria for exclusion below), bronchitis or cystic fibrosis
	  ○ chronic heart disease and vascular disease
	  ○ chronic kidney disease at stage 3, 4 or 5
	  ○ chronic liver disease
	  ○ chronic neurological disease, such as cerebral palsy or motor neurone disease
	  ○ learning disability
	  ○ diabetes and adrenal insufficiency
	  ○ asplenia or dysfunction of the spleen
	  ○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)
	  ○ morbidly obese individuals (aged from 16 years) with a BMI ≥ 40kg/m^2 and above
	
	• children and adolescents from 2 years to under 18 years of age who are close household contacts of immunocompromised individuals. This would also include individuals who expect to share living accommodation on most days over the winter with immunocompromised individuals and therefore for whom continuing close contact is unavoidable. This may include carers.
	
	Note: close contacts (example household members or carers) of **very severely** immunocompromised individuals, for example bone marrow transplant individuals requiring isolation, should receive inactivated influenza vaccine and not LAIV, see the 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
	
	• frontline staff from 16 years to under 18 years of age without employer-led occupational health schemes employed:
	
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Criteria for inclusion (continued)	○ by a registered residential care or nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable individuals who are at increased risk from exposure to influenza ○ by a voluntary managed hospice provider, who are directly involved in the care of vulnerable individuals who are at increased risk from exposure to influenza ○ through Direct Payments (personal budgets) or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to individuals ○ to deliver social care services and are in direct contact with those who are clinically vulnerable to flu, who receive care and support services from the social care provider
Criteria for exclusion[2]	Individuals (or their parents or carers) who have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). For further information on consent, see Chapter 2 of the Green Book. Several resources are available to inform consent (see written information to be given to individual, parent or carer section). LAIV must not be given under this PGD to: • 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 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, 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 UKHSA 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 offered vaccination as part of an employer's occupational health scheme **Refer to the UKHSA Inactivated influenza PGD for the following groups of excluded individuals:** • individuals who are clinically severely immunodeficient due to a condition or immunosuppressive therapy such as: ○ acute and chronic leukaemias ○ lymphoma

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[2] 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)	○ HIV, which is not suppressed by antiretroviral therapy ○ cellular immune deficiencies ○ high dose corticosteroids (prednisolone at least 2mg/kg/day for a week or 1mg/kg/day for a month or equivalent) • individuals for whom close contact with very severely immunocompromised individuals (for instance, bone marrow transplant individuals requiring isolation) is likely or unavoidable (for example, household members) **Temporary exclusions** 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 individual 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 or who are living with HIV may not make a full antibody response to the vaccine.
Action to be taken if the individual 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 UKHSA Inactivated influenza PGD). Children and adolescents with a history of severe anaphylaxis to egg which has required intensive care should ideally be referred to specialists for potential LAIV immunisation in hospital. LAIV remains the preferred vaccine for this group and the intranasal route is less likely to cause systemic reactions. Egg-allergic individuals can alternatively be given the egg-free cell-based quadrivalent inactivated vaccine (QIVc), see the UKHSA 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). Fluenz® contains less than 0.024 micrograms ovalbumin per dose, equivalent to less than 0.12 micrograms per ml and is classed as having a very low ovalbumin content. 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 UKHSA Inactivated influenza PGD). No data exist in reference to the safety of intranasal administration of Fluenz® in individuals with unrepaired craniofacial malformations. In such cases, LAIV may be considered unsuitable and therefore the inactivated influenza vaccine should be offered instead (see the UKHSA Inactivated influenza PGD). All pregnant individuals should be offered inactivated influenza vaccine unless otherwise contraindicated (see the UKHSA 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 UKHSA Inactivated Influenza PGD).

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Action to be taken if the individual is excluded (continued)	This PGD covers NHS commissioned services only. This PGD does not cover the provision of occupational health schemes or peer-to-peer influenza immunisation (see NHS Specialist Pharmacy Service Influenza vaccine written instruction templates for adoption) Individuals temporarily excluded may be offered LAIV at a later date. In case of postponement, arrange a future date for vaccination. Individuals suffering from heavy nasal congestion could be given an intramuscular influenza vaccine instead. 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, should be offered an inactivated influenza vaccine to avoid delaying protection in this high-risk group (see the UKHSA 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 individual's GP or a prescriber as appropriate.
Action to be taken if the individual, parent 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. For further information on consent, see Chapter 2 of the Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications. If the parent or carer of an eligible child refuses LAIV because of its porcine gelatin content (and they understand that it is the most effective product in the programme), advise the individual, parent or carer they can request an alternative injectable vaccine. UKHSA has procured QIVc for these children. Refer to the UKHSA 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

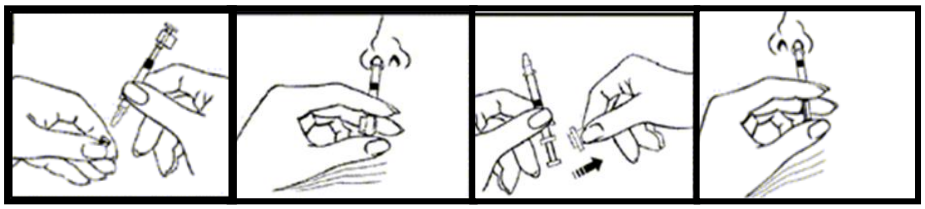
Name, strength and formulation of drug	Live attenuated influenza vaccine nasal spray suspension (0.2ml): • Fluenz® in pre-filled single-use nasal applicator
Legal category	Prescription only medicine (POM)
Black triangle▼	No.
Off-label use	The SPC states children who have not previously been vaccinated against seasonal influenza should be given a second dose 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® 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 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). Vaccines 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 Vaccine Incident Guidance. Where vaccines are 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 or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.
Route and 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. Do not use with a needle. Do not inject. Single application in each nostril of 0.1ml. Do not use Fluenz® if the expiry date has passed or the sprayer appears damaged, for example, if the plunger is loose or displaced from the sprayer or if there are any signs of leakage. Check the appearance of the vaccine before administration. The suspension should be colourless to pale yellow, clear to opalescent. Small white particles may be present. In instances where there is variation of expected appearance of the vaccine prior to preparation and administration, discard the vaccine in accordance with local procedures. The individual can breathe normally during vaccine administration and there is no need to actively inhale or sniff.

<table>
<tr><td>Route and method of administration (continued)</td><td>
Administration does not need to be repeated if the individual sneezes or blows their nose immediately following administration.

Check product name, batch number and expiry date before administration.

The SPC provides further guidance on administration.

Instructions for administration


<table>
<tr><td>Remove the rubber tip protector.
Do not remove the dose-divider clip at the other end.</td><td>With the patient upright, position the tip just inside the nostril and in a single motion, depress the plunger as rapidly as possible until the dose-divider clip prevents movement.</td><td>For administration into the other nostril, pinch and remove the dose-divider clip from the plunger.</td><td>Place the tip just inside the other nostril. In a single motion, depress the plunger as rapidly as possible to deliver the remaining vaccine.</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 years to less than 9 years who are in a clinical risk group category listed in Chapter 19 of 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.

Children aged 2 years to less than 9 years who are household contacts of immunocompromised individuals should be vaccinated in accordance with the advice on children in clinical risk groups (see Chapter 19).

Second dose: 0.2ml of LAIV, administered as 0.1ml in each nostril.

If LAIV is unavailable for second doses, for example due to batch expiry, then offer an age-appropriate and available inactivated influenza vaccine (see UKHSA Inactivated influenza PGD)
</td></tr>
<tr><td>Duration of treatment</td><td>As outlined in dose and frequency of administration above.</td></tr>
<tr><td>Quantity to be supplied or 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.
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Supplies	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 the 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 once, for a maximum period of 12 hours at a temperature not above 25°C. Data indicates the vaccine components are stable for 12 hours at temperatures between 8°C and 25°C. If the vaccine has not been used within this 12 hour period, it should be immediately discarded, in line with local clinical waste procedures. In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste 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 UN-approved waste receptacle (usually a sharps box), according to local authority arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste.
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 affect the response to 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 vaccines (both live and inactivated). Live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment (see Chapter 19). A detailed list of drug interactions is available from the vaccine's SPC.
Identification and management of adverse reactions	Very common adverse reactions observed after administration of LAIV are decreased appetite, nasal congestion, rhinorrhoea and malaise. Commonly encountered reactions include myalgia, headache and pyrexia. The incidence of hypersensitivity reactions (including urticaria and facial oedema), rash and epistaxis are considered to be uncommon. A detailed list of adverse reactions is available from the vaccine's SPC.
Reporting procedure of adverse reactions (continued over page)	Healthcare professionals and individuals, parents or carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for

Reporting procedure of adverse reactions (continued)	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 individual or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. 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. Offer promotional material as appropriate: • protecting your child against flu leaflet • a guide to immunisation for pre-school leaflet • protect yourself from flu, have the flu vaccine: information for people with a learning disability leaflet • the flu vaccination: who should have it and why (as updated for winter 2024 to 2025) For information leaflets in accessible formats and alternative languages, please visit Home- Health Publications. If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC.
Advice and follow-up treatment	Inform the individual, parent or carer of possible side effects and their management. The individual, parent or carer should be advised when to seek medical advice in the event of a severe adverse reaction and encouraged to report this via the Yellow Card reporting scheme. When applicable, advise the individual, parent or carer when the subsequent dose is due. The individual, parent or carer should be advised not to give acetylsalicylic acid or salicylates (a substance present in many medicines used to relieve pain and lower fever) to the child or adolescent for 4 weeks after vaccination with Fluenz® as there is a risk of Reye's syndrome. However, topical treatment containing acetylsalicylic acid or salicylates for localised conditions can be used. The individual, parent or 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 one to 2 weeks following vaccination. If the PGD is used for supply only, advise the individual, parent or carer of the process they need to follow for subsequent administration, for instance refer them immediately to an appropriately trained healthcare support worker (HCSW) within the clinic setting. When administration is postponed, advise the individual, parent or carer when to return for vaccination.
Special considerations and 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. For further information on consent, see Chapter 2 of the Green Book.

Special considerations and additional information (continued)	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 is not contraindicated for use in children or adolescents living with HIV receiving antiretroviral therapy and attaining viral suppression. Other eligible individuals include those who are receiving topical corticosteroids, inhaled corticosteroids, low-dose systemic corticosteroids or those receiving corticosteroids as replacement therapy (such as for adrenal insufficiency). This PGD may be used for these individuals. Individuals with learning disabilities may require reasonable adjustments to support vaccination (see Flu vaccinations: supporting people with learning disabilities). LAIV should be offered to eligible children aged from 2 years to less than 18 years of age. Where parents object to LAIV on the grounds of its porcine gelatine content or where LAIV is unsuitable, children should be offered the injectable cell-based quadrivalent influenza vaccine (QIVc), see the UKHSA Inactivated 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 or carer. The HCSW cannot supply the medicine. Children with cochlear implants can be given LAIV safely although ideally not in the week prior to implant surgery or for 2 weeks afterwards, or if there is evidence of ongoing cerebrospinal fluid leak. **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)	The practitioner must ensure the following is recorded: • 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) • 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 the individual is 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 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.

Records (continued)	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 3 November 2023. Guidance: Influenza: the green book, chapter 19 • Summary of Product Characteristics: Fluenz® trivalent nasal spray suspension, published 26 June 2024 https://www.medicines.org.uk/emc/product/15790/smpc • Collection: Annual Flu Programme https://www.gov.uk/government/collections/annual-flu-programme . • The national flu immunisation programme 2024 to 2025 letter, published 12 March 2024 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2024-to-2025/national-flu-immunisation-programme-2024-to-2025-letter • Statement of amendment to the annual flu letter for 2024 to 2025, published 12 June 2024, updated 18 June 2024 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2024-to-2025/statement-of-amendment-to-the-annual-flu-letter-for-2024-to-2025-12-june-2024 • Influenza vaccine written instruction templates for adoption. NHS Specialist Pharmacy Service, published 4 March 2024 https://www.sps.nhs.uk/articles/influenza-vaccine-written-instruction-templates-for-adoption/ • Flu immunisation training recommendations, updated 8 August 2023 https://www.gov.uk/government/publications/flu-immunisation-training-recommendations • 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** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • Immunisation Against Infectious Disease: The Green Book. Chapter 2, updated 12 October 2023 https://www.gov.uk/government/publications/consent-the-green-book-chapter-2 • National Minimum Standards and Core Curriculum for Immunisation Training, published 7 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, updated 27 March 2017 https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection. www.gov.uk/government/collections/immunisation (www.gov.uk) • Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

LAIV PGD v14.00 Valid from: 1 September 2024 Expiry: 1 April 2025

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.