



NHS publishing approval reference: PRN02117

Community Pharmacy Influenza vaccine (2 and 3 years of age) Patient Group Direction (PGD)

This PGD is for the administration of live attenuated influenza vaccine (LAIV) nasal spray suspension as the first line vaccine and cell-cultured inactivated influenza vaccine (IIVc) to children aged 2 and 3 years old within a community pharmacy setting, in accordance with the childhood seasonal influenza vaccination advanced service specification and the national influenza immunisation programme.

The user must be competent in administration of the LAIV vaccine via the intranasal route and administering IIVc via the intramuscular route, as outlined in section 3.

The PGD is for the administration of LAIV or IIVc by registered healthcare practitioners identified in section 3, subject to any limitations to authorisation detailed in section 2.

Reference no: Community Pharmacy Influenza vaccine PGD (2 and 3 years of age)

Version no: v1.0

Valid from: 1 October 2025 Expiry date: 1 April 2026

The UK Health Security Agency (UKHSA) has developed this PGD for authorisation by NHS England to facilitate delivery of the national immunisation programme in England.

NHS England and community pharmacy contractors must not alter or amend the clinical content of this document (sections 3,4,5 and 6); such action will invalidate the clinical sign-off with which it is provided. Section 2 may be amended by NHS England only. Section 7 is to be completed by the community pharmacy contractor providing the advanced service. 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 NHS England as the commissioner and the community pharmacy contractor as the service provider. The final authorised copy of this PGD should be kept by NHS England and community pharmacy contractors for 25 years after the PGD expires.

Individual registered practitioners must be authorised by name to work according to the current version of this PGD by signing section 7. A manager with the relevant level of authority should also provide a countersignature unless there are contractual arrangements for self-declaration. Providers are also reminded to ensure vaccination is in line with the contractual arrangements and limitations of service provision agreed with the service commissioner as well as the criteria for inclusion.

Providers must check that they are using the current version of this PGD. Amendments may become necessary prior to the published expiry date. The current version of the community pharmacy childhood seasonal influenza vaccination advanced service PGD can be found at: NHS England » Community Pharmacy Seasonal Influenza vaccine service.

Any enquiries regarding this PGD should be addressed to: ENGLAND.communitypharmacy@nhs.net

Change history

Version number	Change details	Date
v1.0	New UKHSA combined PGD to support delivery of the national influenza immunisation programme to children 2 and 3 years of age in community pharmacies, in accordance with the amended flu letter.	29 August 2025

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 Programmes Division, UKHSA	Chichan	21 August 2025
Doctor	Dr Alex Allen Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA	Aux Au	21 August 2025
Registered Nurse (Chair of Expert Panel)	Greta Hayward Consultant Midwife for Immunisation Programmes, Immunisation Programme Division, UKHSA	J.J. Hag .	21 August 2025

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

Expert Panel (continued overleaf)

Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA	
Jessica Baldasera	Health Protection Practitioner, North East Health Protection Team, Regions Directorate, UKHSA	
Helen Beynon	Clinical Advisor, Immunisation Clinical Advice Response Service (CARS), NHS England London	
Alastair Buxton	Director of NHS Services, Community Pharmacy England	
Alison Campbell	Screening and Immunisation Coordinator, Public Health Commissioning NHS England - Midlands	
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy NHS England	
Rosie Furner	Advanced Specialist Pharmacist - Medicines Governance (Patient Group directions and Medicines Mechanisms), NHS Specialist Pharmacist Services (SPS)	
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based, Southbourne Surgery	
Shilan Ghafoor	Lead Pharmacist - Medicines Governance, UKHSA	
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board	
Elizabeth Luckett	Senior Screening and Immunisation Manager, Screening and Immunisation Team – Kent and Medway, NHS England - South East	
Dr Suzanna McDonald	National Programme Lead for Influenza Immunisation, Immunisation Programmes Division, UKHSA	
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation Programmes Division, UKHSA	

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Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Briony Mason	Vaccination Manager, Professional Midwifery Advocate, Vaccination and Screening, NHS England - West Midlands
David Onuoha	Service Development Manager, Community Pharmacy England
Tushar Shah	Lead Pharmacy Adviser, NHS England - London

2. Organisational authorisations

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

NHS England accepts responsibility for governance of this PGD. Any community pharmacy contractor providing the advanced service must work strictly within the terms of this PGD and the community pharmacy childhood seasonal influenza vaccination advanced service specification. Any deviation will be treated as a serious contractual breach.

NHS England authorises this PGD for use by community pharmacy contractors delivering the community pharmacy seasonal influenza vaccination advanced service specification for children 2 and 3 years of age.

Organisational approval (legal requirement)				
Role	Name	Signature	Date	
Director of Vaccination, NHS England	Caroline Temmink	Corie Zen	26 August 2025	

Enquiries regarding the use of this PGD may be directed to: ENGLAND.communitypharmacy@nhs.net

The community pharmacy contractor must complete the practitioner authorisation sheet included at the end of this PGD (see <u>section 7</u>). Alternative practitioner authorisation sheets, specifying the PGD and version number, may be used where appropriate in accordance with local policy. This may include the use of electronic records.

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3. Characteristics of staff

Qualifications and professional registration

All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the <u>additional requirements</u> and <u>continued training requirements</u> to ensure their competency is up to date, as outlined in the section below.

Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD:

- pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is only relevant to the national community pharmacy childhood seasonal influenza vaccination advanced service specification. This PGD cannot be used for privately provided community pharmacy services).
- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- 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

Additional requirements

Additionally, practitioners:

- must be authorised by name as an approved practitioner under the current terms of this PGD before working to it (by completion of section 7)
- must have undertaken appropriate training for working under PGDs for supply and administration of medicines as required by the community pharmacy childhood seasonal influenza vaccination advanced service specification
- must be competent in the use of PGDs (see <u>NICE Competency framework for health professionals using PGDs</u>)
- must be familiar with the vaccine product and alert to changes in the Summary
 of Product Characteristics (<u>SPC</u>), Immunisation Against Infectious Disease (the
 <u>Green Book</u>) and the national immunisation programmes
- must have undertaken training appropriate to this PGD as required by local policy and in line with the <u>National Minimum Standards and Core Curriculum for</u> Immunisation Training
- must be competent in both intramuscular and intranasal administration techniques
- must be competent to undertake immunisation and to discuss issues related to seasonal influenza 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
- must be accountable for their practice

The healthcare professional authorising manager must be satisfied that the practitioners named in <u>section 7</u> have the suitable training, knowledge and skills to provide the service as outlined in <u>UKHSA</u>

<u>National Minimum Standards and Core Curriculum for Vaccination</u> to work under this PGD.

The practitioner must be authorised by name, under the current NHS England authorised version of this PGD before working under its authority

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 and other sources of medicines information.

Note: The most current national recommendations should be followed. However, if updated recommendations mean that to vaccinate the individual would be outside the criteria of this PGD, the individual should be referred to their GP practice for vaccination.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies

LAIV and IIVc are indicated for the active immunisation of children from 2 years to 3 years of age for the prevention of influenza infection. These vaccines are offered in accordance with, the national immunisation programme and recommendations given in Chapter 19 of Immunisation Against Infectious Disease: the Green Book, annual flu letter(s), subsequent flu letter amendments, the specification and subsequent correspondence and publications from UKHSA and NHS England.

Criteria for inclusion

Community pharmacy providers are reminded to ensure vaccination is in line with the contractual arrangements and limitations of service provision agreed with the service commissioner, as well as the criteria for inclusion. Providers are also accountable for ensuring vaccinators listed under section 7 are trained and clinically competent to deliver such services and are assured that the training requirements in section 3 are complete prior to commencing vaccination

For the 2025 to 2026 influenza season, LAIV (or IIVc if LAIV is unsuitable or contraindicated) should be offered under the NHS influenza immunisation programme and in accordance with the community pharmacy childhood seasonal influenza vaccination advanced service specification.

From 1 October:

 all those aged 2 or 3 years on or before 31 August 2025, including clinically at-risk 2 or 3 year olds. These children will have a date of birth on or after 1 September 2021 and on or before 31 August 2023

Criteria for exclusion¹

Individuals for whom no valid consent has been received (or for whom a best-interests decision in accordance with the <u>Mental Capacity Act 2005</u>, has not been obtained). For further information on consent, see <u>Chapter 2</u> of the Green Book. Several resources are available to inform consent (see <u>written information</u> to be given to parent or carer section).

Exclusion criteria for all individuals:

- children and infants under 2 years and over 3 years of age on 1 September 2025. These children have a date of birth on or before 31 August 2021, or on or after 1 September 2023
- individuals who have received a complete dose of the recommended influenza vaccine for the current season, unless they are:
 - aged 2 or 3 years and are in a clinical risk group listed in <u>Chapter 19</u>
 of the Green Book
 - o are household contacts of individuals with immunosuppression

In the first season the above individuals are vaccinated against influenza (in other words, they have never previously received an influenza vaccine before this season), they should receive a second dose of an appropriate influenza vaccine at least 4 weeks after the first dose

Exclusion criteria for LAIV (consider offering IIVc vaccine instead):

 individuals with a confirmed anaphylactic reaction to a previous dose of influenza vaccine

(continued over page)

 individuals with a confirmed anaphylactic reaction to any component of LAIV (such as gelatine) or residue from the manufacturing process (such as

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¹ 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 exclusion²

(continued)

- gentamicin), with the exception of egg proteins (see <u>action to be taken if the individual is excluded</u> section)
- individuals with severe anaphylaxis to egg which has previously required intensive care
- individuals with egg allergy (less severe than anaphylaxis requiring intensive care) but who also have another condition which contraindicates LAIV
- 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
- individuals for whom LAIV is not suitable due to the parent or carer's nonacceptance of its porcine gelatine content
- individuals who are clinically severely immunodeficient due to a condition or immunosuppressive therapy such as:
 - o acute and chronic leukaemias
 - lymphoma
 - o HIV, which is not suppressed by antiretroviral therapy
 - o 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 for LAIV

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 <u>action to</u> 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

Exclusion criteria for IIVc:

- have had a confirmed anaphylactic reaction to a previous dose of IIVc or to any of its components or residues from the manufacturing process
- the child is suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

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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.

Cautions including any relevant action to be taken

Facilities for management of anaphylaxis should be available at all vaccination sites (see <u>Chapter 8</u> of the Green Book and advice issued by the <u>Resuscitation</u> Council UK).

Individuals who have immunosuppression or who are living with HIV may not make a full antibody response to the vaccine.

Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Action to be taken if the individual is excluded

The risk to the individual of not being immunised must be taken into account. The indications for flu vaccination are not exhaustive, and the healthcare practitioner should consider the risk of flu exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from flu itself. Where appropriate, such individuals should be referred to their GP practice.

Children 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 IIVc.

Children with a history of severe anaphylaxis to egg which has required intensive care should ideally be referred to specialists via their GP 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 IIVc. The Joint Committee on Vaccination and Immunisation (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 IIVc.

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 IIVc should be offered instead.

Vaccination with IIVc should be considered for immunosuppressed individuals excluded from receiving LAIV and those who are contacts of individuals who are very severely immunocompromised.

Individuals temporarily excluded may be offered LAIV at a later date. In case of postponement, arrange a future date for vaccination. Individuals 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 IIVc to avoid delaying protection in this high-risk group.

In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or individual's clinician as required.

(continued)

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Action to be taken if	The risk to the individual of not being immunised must be taken into account.		
the individual is excluded	Document the reason for exclusion and any action taken in the individual's clinical records.		
(continued over page)	Inform or refer to the individual's GP practice or a prescriber as appropriate.		
Action to be taken if the parent or carer declines treatment	Informed consent, from a person legally able to act on the individual's behalf, must be obtained for each administration and recorded appropriately. For further information on consent, see Chapter 2 of the Green Book.		
	Advise the parent or carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.		
	If the parent or carer 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 parent or carer they can request IIVc as an alternative injectable vaccine, if it is available.		
	Document the advice given and decision reached.		
	Inform or refer to the child's GP practice as appropriate.		
Arrangements for referral for medical advice	Refer to the child's GP practice.		

5. Description of treatment

Name, strength and	First line: LAIV nasal spray suspension:	
formulation of drug	Fluenz [®] in pre-filled single-use nasal applicator.	
	The vaccine may contain residues of the following substances: egg proteins (e.g. ovalbumin) and gentamicin. The maximum amount of ovalbumin is less than 0.024 micrograms per 0.2 ml dose (0.12 micrograms per ml).	
	 Second line: Inactivated influenza vaccine suspension in a pre-filled syringe. cell-cultured inactivated influenza vaccine (IIVc) ▼ where LAIV is medically contraindicated or otherwise unsuitable. 	
Legal category	Prescription only medicine (POM)	
Black triangle ▼	IIVc.	
	Being a newer vaccine, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for IIVc.	
	All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme.	
	This information was accurate at the time of writing. See the product SPC for indication of current black triangle status.	
Off-label use	Both the LAIV and IIVc SPCs recommend a second dose for children aged under 9 years, 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 or IIVc irrespective of whether they have received influenza vaccine previously.	
	Fluenz® is contraindicated in children 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.	
	Fluenz® is contraindicated in children with severe asthma, however, JCVI have advised children with asthma on inhaled corticosteroids may safely be given LAIV, irrespective of the dose prescribed.	
	Vaccines should be stored according to the conditions detailed in the <u>storage</u> section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to <u>Vaccine Incident Guidance</u> . 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, as part of the consent process, consider informing the parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.	

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Route and method of administration

Vaccinators must ensure they are trained and competent to administer the vaccine via the preferred route, to the cohort(s) they have been commissioned to vaccinate.

Practitioners named in <u>section 7</u> must have the suitable training, knowledge and skills to provide the service as per the <u>UKHSA National Minimum</u> <u>Standards and Core Curriculum for Vaccination</u> and work under this PGD. Administration under this PGD must be directly by the registered health professional named in <u>section 7</u>.

LAIV administration

LAIV is for **intranasal application** only.

Do not use with a needle. Do not inject.

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

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.

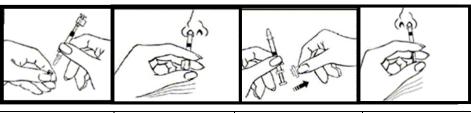
The individual can breathe normally during vaccine administration and there is no need to actively inhale or sniff.

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



		. •	
Remove the rubber tip	With the patient upright, position	For administration into the other	Place the tip just inside the
protector.	the tip just inside	nostril, pinch and remove the dose-	other nostril.
Do not remove the dose-	a single motion, depress the	divider clip from the plunger.	motion, depress the
divider clip at the other end.	plunger as	tile pluriger.	plunger as
the other end.	rapidly as possible until the		rapidly as possible to
	dose-divider clip prevents		deliver the remaining
	movement.		vaccine.

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Route and method of administration

(continued)

IIVc administration

Administer by intramuscular injection, preferably into the deltoid muscle of the upper arm.

When co-administering with other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably into different limbs. If given into the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (23 gauge or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy.

The parent or carer should be informed about the risk of haematoma from the injection.

Note: IIVc is not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD.

The site at which each vaccine was given should be noted in the individual's records. Shake vaccine suspensions gently before administration.

Visually inspect the vaccine prior to administration for any foreign particulate matter, discolouration or other variation of expected appearance from that described in the vaccine's <u>SPC</u>. Discard the vaccine in accordance with local procedures, should any of these occur.

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

The SPC provides further guidance on administration.

Dose and frequency of administration

First line: Single dose of 0.2ml of LAIV, administered as 0.1ml into each nostril, to be administered between 1 October 2025 and 31 March 2026.

Second line: If LAIV is contraindicated or otherwise unsuitable on the grounds of its porcine gelatine content, a single 0.5ml dose of IIVc should be administered via the intramuscular route between 1 October 2025 and 31 March 2026.

Second doses for children in clinical risk groups or who are household contacts of immunocompromised individuals (of any age)

Children aged between 2 and 3 years of age who are in a clinical risk group category listed in <u>Chapter 19</u> of the Green Book **and** who have not received a dose of any influenza vaccine before should receive 2 doses of LAIV (or IIVc), the second at least 4 weeks after the first dose.

Children aged between 2 and 3 years of age who are household contacts of immunocompromised individuals of any age **and** who have not received a dose of any influenza vaccine before should receive 2 doses of LAIV (or IIVc), the second at least 4 weeks after the first dose.

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Dose and frequency of administration	Second dose : 0.2ml of LAIV, administered as 0.1ml in each nostril at a minimum interval of 4 weeks after the first dose.		
(continued)	If LAIV is unavailable for second doses, for example due to batch expiry, then offer IIVc, as a 0.5ml dose via the intramuscular route.		
	Though outlined as a third line option for this age group in the <u>annual flu</u> <u>letter</u> , IIVe may not be given under this PGD.		
Duration of treatment	As outlined in dose and frequency of administration above.		
Quantity to be	First line		
supplied or administered	LAIV: 0.2ml dose to be administered as 0.1ml into each nostril		
	Second line		
	IIVc: single dose of 0.5ml per administration.		
	See <u>dose and frequency section</u> for full details.		
Supplies	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).		
	NHS England's Federated Data Platform (<u>FDP</u>) should be used to order LAIV.		
	In the event that LAIV is not suitable, contractors are expected to use IIVc from stocks procured earlier in the flu season, for other eligible cohorts.		
Storage	Store at +2°C to +8°C. Do not freeze.		
	Store in original packaging in order to protect from light.		
	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 .		
	Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.		
	LAIV only:		
	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 LAIV has not been used within this 12 hour period, it should be immediately discarded, in line with local clinical waste procedures.		
Disposal	Follow local clinical waste policy and Community Pharmacy 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 in a UN-approved waste receptacle (usually a sharps box), according to waste disposal arrangements and NHS England guidance (HTM 07-01): safe and sustainable management of healthcare waste.		
Drug interactions	The immunological response may be diminished in those receiving immunosuppressive treatment, but it is still important to immunise this group.		
(continued over page)	There is a potential for influenza antiviral agents to lower the effectiveness of the LAIV. Therefore, influenza antiviral agents and LAIV should not be administered concomitantly. LAIV should be delayed until 48 hours following the cessation of treatment with influenza antiviral agents.		

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Drug interactions Administration of influenza antiviral agents within the 2 weeks following administration of LAIV may affect the response to the vaccine. (continued) 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 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). IIVc may be given at the same time as other vaccines, including COVID-19. A detailed list of drug interactions is available from the vaccine's SPC. Identification and LAIV management of Very common adverse reactions observed after administration of LAIV are adverse reactions 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. IIVc The most commonly observed reactions in children are injection site pain, erythema, induration and ecchymosis, headache, fatigue, myalgia and loss of appetite. A detailed list of adverse reactions is available from the vaccine's SPC. Healthcare professionals, parents and carers are encouraged to report Reporting procedure suspected adverse reactions to the Medicines and Healthcare products of adverse reactions Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching 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 Offer the marketing authorisation holder's patient information leaflet (PIL) to be given to the provided with the vaccine. parent or carer 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

 the flu vaccination: who should have it and why (as updated for winter 2025 to 2026)

For information leaflets in accessible formats and alternative languages, please visit Home-Health Publications. If applicable, inform the 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 SPC.

Advice and follow-up treatment

Inform the parent or carer of possible side effects and their management.

The parent or carer should be advised when to seek medical advice in the

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Advice and follow-up treatment

(continued)

event of a severe adverse reaction and encouraged to report this via the Yellow Card reporting scheme.

For children who have not received an influenza dose before and require a second dose after a minimum of 4 weeks (see <u>dose and frequency of administration</u>), advise the parent or carer when the subsequent dose is due.

The 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 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 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.

When administration is postponed, advise the parent or carer when to return for vaccination.

Special considerations and additional information

General points

Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and easy access to a telephone.

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.

Individuals not registered with a GP practice may be vaccinated, weighing up risks and benefits for the individual. They should be encouraged to register with a GP as appropriate to their circumstances or be referred to appropriate alternative medical services as required.

Individuals with learning disabilities may require reasonable adjustments to support vaccination (see <u>Flu vaccinations: supporting people with learning disabilities</u>).

Considerations for LAIV

LAIV is not contraindicated for use in children 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). LAIV may be given to these individuals.

Where parents or carers object to LAIV on the grounds of its porcine gelatine content or where LAIV is unsuitable, children should be offered IIVc instead.

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 to LAIV

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

The practitioner must ensure the following is recorded:

- that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the <u>Mental Capacity Act</u> 2005
- 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
- dose, form and route of administration of vaccine
- quantity administered
- batch number and expiry date
- anatomical site of vaccination where IIVc was given
- advice given, including advice given if the individual is excluded or immunisation is declined
- details of any adverse drug reactions and actions taken
- administered via PGD

Records should be signed and dated or if using electronic records, the immuniser's account should be password protected to append an electronic signature to the vaccination record.

All records should be clear, legible and contemporaneous and in line with the community pharmacy childhood seasonal influenza vaccination advanced service specification.

As a wide variety of influenza vaccines are available on the UK market each year, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records.

It is important that vaccinations administered are recorded in a timely manner. A record of the vaccination should be returned to the individual's general practice to 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 and post-payment verification.

6. Key references

Key references

LAIV

 Summary of Product Characteristics: Fluenz[®] trivalent nasal spray suspension, 21 July 2025
 www.medicines.org.uk/emc/product/15790/smpc

IIVc

- Summary of Product Characteristics <u>TIVc (IIVc)</u>, Seqirus[®] UK, last updated 11 July 2025
- Immunisation Against Infectious Disease: the Green Book. Chapter 19
- Collection: Annual Flu Programme www.gov.uk/government/collections/annual-flu-programme
- Amendment to national flu immunisation programme 2025 to 2026 letter, published 28 July 2025 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2025-to-2026-letter
- The national flu immunisation programme 2025 to 2026 letter, published 13
 February 2025
 www.gov.uk/government/publications/national-flu-immunisation-programmeplan-2025-to-2026/national-flu-immunisation-programme-2025-to-2026-letter
- Flu vaccinations: supporting people with learning disabilities, updated 25
 September 2018
 www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities
- Workforce planning and models of delivery toolkit
 Workforce planning and models of delivery toolkit-Extension of the national fluimmunisation programme to children
- Community pharmacy advanced service specification childhood seasonal influenza vaccination 1 October 2025 to 31 March 2026, published 23 July 2025 https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service/

General

- NHS England Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste
 www.england.nhs.uk/publication/management-and-disposal-of-healthcarewaste-htm-07-01/
- Immunisation Against Infectious Disease: The Green Book. Chapter 2 https://www.gov.uk/government/publications/consent-the-green-book-chapter-2
- National Minimum Standards and Core Curriculum for Immunisation Training, updated 23 June 2025
 www.gov.uk/government/publications/national-minimum-standards-and-corecurriculum-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

(continued over page)

Key references (continued)

Vaccine Incident Guidance
 <u>www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</u>

7. Practitioner authorisation sheet

Community Pharmacy Influenza vaccine PGD (2 and 3 years of age) v1.0 Valid from: 1 October 2025 Expiry: 1 April 2026

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.

Authorising manager

I confirm that the registered healthcare professionals 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.

A copy of this PGD with a completed practitioner authorisation sheet should be retained and available at the pharmacy premises as a record of those practitioners authorised to work under this PGD.