NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Protocol For The Administration Of Live Attenuated Intranasal Influenza Vaccine (LAIV) 2024/25 season, By Non-Registered Staff Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Version 4.0 - 2024/25

Effective from 1st September 2024

NoS/Protocol/LAIV/1543

Note: Inactivated influenza vaccines are not covered by this protocol – separate protocol is available.

Version history

Version	Date	Summary of changes
4.0	20th August 2024	Vaccine changed from Quadrivalent (Fluenz Tetra) to Trivalent (Fluenz)
4.0	20th August 2024	Dates for 2024-25 season updated throughout the document.

Contents

Authorisation

Approved and authorised for use within NoS by;

North of Scotland (NoS) Patient Group Direction (PGD) Chair	Signature	Date Signed
Lesley Coyle		22/08/2024

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells - Interim Chief Executive PP: June Brown, Deputy Interim Chief Executive		27/08/2024

This protocol has been developed by NHS Grampian. NoS Boards should amend/adapt this protocol if required, and must ensure that it is considered and approved in line with local clinical governance arrangements and individual Board immunisation delivery plans.

Management and Monitoring of Protocol

Consultative Group

Name:	Title:
Jodie Allan	**Lead Author:** Medicines Management Specialist Nurse NHSG
Russell Mackay	Clinical Pharmacist NHSO
Dr Claire-Louise Walker	Consultant in Public Health Medicine NHSG
Pauline Merchant	Clinical Nurse Lead, Vaccinations NHSG
Fiona Marion	Vaccine Pharmacist NHSG

Version 4 - Effective from 1st September 2024 review date 1st August 2025

Protocol Important Information

This protocol authorises LAIV to be administered by appropriately trained non-registered members of staff within the clinic setting. Administration is authorised following supply, for subsequent administration, by an approved healthcare professional under the Patient Group Direction For The Supply For Immediate Administration or Administration of Live Attenuated Intranasal Influenza Vaccine (LAIV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles. Registered healthcare professionals and non-registered members of staff involved in a vaccination session are accountable for their own actions. The Registered healthcare professional delegating the task of administration to a suitably trained non-registered member of staff remains accountable for the decision in delegating this task.

Obtaining consent and individual assessment must only be undertaken by a registered healthcare professional as specified in the Patient Group Direction (PGD), this is not covered under this protocol. Only the process of subsequent immediate administration of LAIV may be undertaken by the suitably trained non-registered member of staff. This must be under clinical supervision and on the authority of an approved healthcare professional.

The provider is responsible for ensuring that non-registered members of staff are trained and competent to safely deliver administration of LAIV under this protocol. As a minimum, competence requirements stipulated in the protocol under 'Characteristics of staff' must be adhered to. The provider must identify a clinical supervisor who has overall responsibility for administration of LAIV by suitably trained non-registered members of staff under the protocol at all times.

The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the PGD and protocol and provide clinical supervision for the overall provision of clinical care provided under the protocol. Suitably trained non-registered member of staff working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Suitably trained non-registered member of staff working to the protocol must understand who the clinical supervisor for their practice is at any time and can only work under their authority. The clinical supervisor may withdraw this authority for all persons or individual persons at any time and has authority to stop and start service provision under the protocol as necessary. All members of staff have a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the protocol in general or about a specific individual, process, issue or event.

Individual practitioners must be designated by name to work to this protocol. Individuals working in accordance with this protocol must ensure they meet the staff characteristics for the activity

they are undertaking, make a declaration of competence and be authorised in writing by the provider. This can be done by completing Annex A of this protocol.

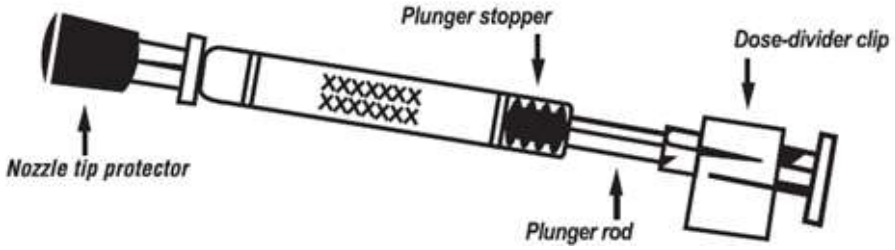
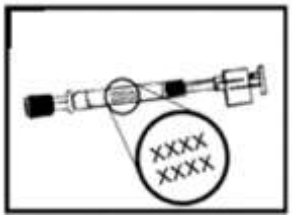
It is the individual Health Board's responsibility to adhere to this protocol. Where the Health Board is not the provider, it is the Health Board's responsibility to ensure that the provider adheres to this protocol. The provider must ensure the suitably trained non-registered member of staff is covered by the employer's indemnity insurance for undertaking this approved task.

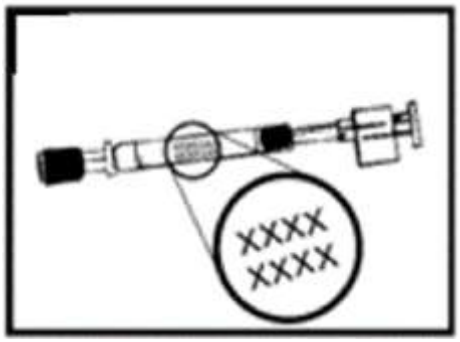
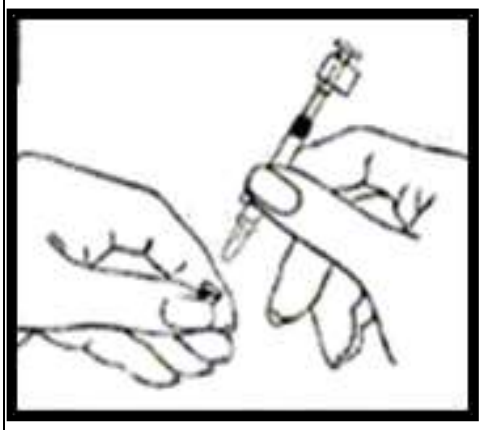
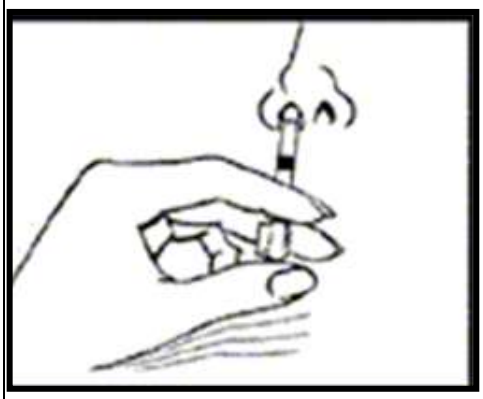
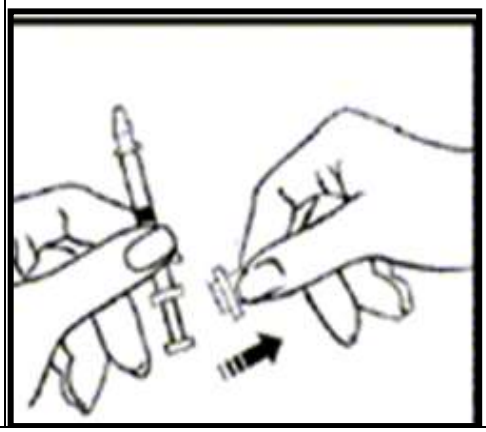
Providers must check that they are using the current version of this protocol. Amendments may become necessary prior to the published expiry date.

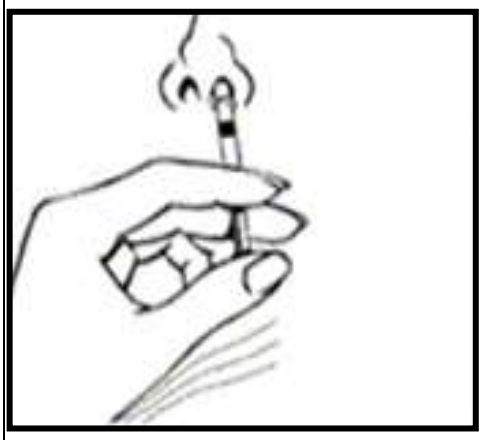
Clinical situation

Category	Description
Indication	Active immunisation against disease caused by influenza virus in line with Scottish Government seasonal influenza immunisation programme 2024/25.
Inclusion criteria	Individuals assessed by registered health care professional as appropriate to receive LAIV vaccination, as per the Patient Group Direction For The Supply For Immediate Administration Or Administration Of Live Attenuated Intranasal Influenza Vaccine (LAIV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles who have been supplied with LAIV for subsequent immediate administration by an approved suitably trained non-registered member of staff under clinical supervision. Valid consent has been given for LAIV vaccine administration by a suitably trained non-registered member of staff.
Exclusion criteria	Individuals not assessed by registered healthcare professional as appropriate to receive LAIV vaccination. LAIV not supplied under the PGD for immediate subsequent administration. No valid consent for vaccine administration by a suitably trained non-registered member of staff.
Cautions/need for further advice/ circumstances when further advice should be sought from a doctor	LAIV supplied by registered healthcare professional to individual for subsequent immediate administration by a suitably trained non-registered member of staff must not be removed from the clinic area. LAIV supplied by registered healthcare professional must be administered immediately by a suitably trained non-registered member of staff in the clinic area. LAIV supplied by registered healthcare professional to individual for subsequent immediate administration by a suitably trained non-registered member of staff does not required to be labelled.
Action if excluded	Refer back to registered healthcare professional, clinical supervisor.
Action if individual declines	Suitably trained non-registered members of staff should refer individual back to registered healthcare professional who assessed the individual and supplied the LAIV for administration.

Description of treatment

Category	Description
Name of medicine/ Legal category	Live attenuated intranasal influenza vaccine (LAIV) Prescription only Medicine (POM) – Fluenz Trivalent®
Form/strength	Nasal spray, suspension in a prefilled nasal applicator 
Dosage	0.2mL (administered as 0.1mL per nostril). LAIV is administered as a divided dose in both nostrils.
Frequency	Children **not** in clinical risk groups only require one dose of LAIV. Children in clinical risk groups aged two to under 9 years who have not received influenza vaccine before should receive two doses of LAIV with the second dose at least 4 weeks after the first – each dose is required to be supplied separately by a registered healthcare professional operating under LAIV PGD.
Storage requirements	Registered Healthcare professionals are responsible for the appropriate storage of LAIV prior to supply for immediate administration as detailed in the PGD. Registered Healthcare professionals must check expiry date prior to supply of LAIV (see below). The product must not be used after date on applicator label  LAIV supplied to an individual for subsequent administration by a suitably trained non-registered member of staff should be administered immediately, it should not be stored or held for future administration.
Additional information	The individual can breathe normally while the vaccine is being administered – there is no need to actively inhale or sniff. Administration of either dose does not need to be repeated if the individual sneezes or blows their nose following administration.

Route of administration	Nasal administration only. LAIV must not be injected. Single application in each nostril of 0.1mL The individual can breathe normally while the vaccine is being administered – there is no need to actively inhale or sniff.  Non-registered member of staff must check the expiry date prior to administration. If it is not within date it must not be administered and the registered healthcare professional, clinical supervisor informed.  Administration under this protocol must be a named, suitably trained non-registered member of staff. The suitably trained non-registered member of staff must wash/clean hands with alcohol gel prior to handing LAIV. Remove protective tip cap. Do NOT remove the dose-divider.  With the individual upright, position the applicator tip just inside the nostril. With a single movement, depress the plunger as rapidly as possible until the dose-divider clip prevents you from going further.  For administration to the other nostril. Pinch and remove the dose-divider clip from the plunger.

Category	Description
	 Place the tip just inside the other nostril and in a single motion, depress the plunger as rapidly as possible to deliver remaining vaccine. Dispose of the nasal syringe in a pharmaceutical waste bin as per board policy. The suitably trained non-registered member of staff should wash/clean hands with alcohol gel at end of the administration process.

Adverse reactions

Category	Description
Reporting procedure for adverse reactions	Suitably trained non-registered member of staff should report any adverse reactions at the point of administration immediately to a registered healthcare professional/clinical supervisor. Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://yellowcard.mhra.gov.uk/. Any adverse reaction to a vaccine should be documented by the Healthcare professional in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.
Advice to individual or carer including written information	Registered healthcare professional is responsible for providing individual with information regarding vaccination. The suitably trained non-registered member of staff should refer individual back to the registered healthcare professional/clinical supervisor if they have any queries regarding the vaccination.
Monitoring	Following immunisation individuals remain under observation in line with NHS board policy.
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. The registered healthcare professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of an individual with anaphylaxis.

Characteristics of staff authorised under the protocol

Category	Description
Staff Category	Suitably trained non-registered members of staff, as identified by individual Health Board, who are supporting the delivery of vaccination services.
Specialist competencies or qualifications	Suitably trained non-registered members of staff must only work under this protocol where they are competent to do so. All persons operating this protocol: • must be authorised by name by their employer as an approved person under the current terms of this protocol before working to it • must be familiar with the vaccine product, handling and the administration process • must be competent to undertake nasal immunisation administration process • must have access to the protocol and associated resources • should fulfil any additional requirements defined by local policy Employer The employer is responsible for ensuring that the suitably trained non-registered member of staff have the required knowledge and skills to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.
Continuing education and training	All suitably trained non-registered members of staff operating under the protocol are responsible for ensuring they remain up to date with the administration of LAIV. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this protocol.

Audit trail

Name	Description
Record/ audit trail	Records for the supply of LAIV for subsequent immediate administration by suitably trained non-registered members of staff are the responsibility of the registered healthcare professional under the terms of the PGD. Records regarding suitably trained non-registered members of staff administration may be kept in line with local procedures. All records should be clear, legible and contemporaneous and in an easily retrievable format.

References

Name	Description
References	Fluenz Trivalent® Nasal spray suspension Influenza vaccine (live attenuated, nasal) - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) Date of revision of text 17/07/24, accessed 20/08/25. RCN Guidance – Health Care Support Workers Administering Inactivated Influenza, Shingles and Pneumococcal Vaccines for Adults and Live Attenuated Influenza Vaccine (LAIV) for Children Version 3. 2022

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ANNEX A: HCSW Authorisation Sheet

Protocol For The Administration Of Live Attenuated Intranasal Influenza Vaccine (LAIV) 2024/25 season By Suitably Trained Non-Registered Staff Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Version 4.0 (Valid from1st September 2024)

Practitioner

By signing this Protocol you are indicating that you agree to its contents and that you will work within it.

Suitably trained non-registered staff are accountable for their practice during vaccine administration.

It is the responsibility of each suitably trained non-registered member of staff to practise only within the bounds of their own competence.

I confirm that I have read and understood the content of this Protocol and that I am willing and competent to work to it.			
Name	Designation	Signature	Date

Person authorising on behalf of Provider

I confirm that the non-registered staff named above have declared themselves suitably trained and competent to work under this Protocol. I give authorisation on behalf of _____(**insert name of organisation)** for the above named health care professionals who have signed the Protocol to work under it.			
Name	Designation	Signature	Date

Note to person authorising on behalf of Provider

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 Protocol.