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

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

Version 1.1 2022/23

Effective from 22nd September 2022

NoS/PGD/LAIV/MGPG1291

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

This Patient Group Direction (PGD) has been adopted from the PGD template produced by Public Health Scotland on 5th August 2022 and 22nd September 2022.

Most recent changes

Version	Date	Summary of changes
V1.1	22 September 2022	Exclusion section wording on those with HIV updated to align with wording in Green Book chapter 19 Cautions section updated to align with wording in Green Book chapter 19 for those with cochlear implants

Contents

Authorisation

PGD Live Attenuated Intranasal Influenza Vaccine (LAIV)

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS boards. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may supply for immediate administration or administer Live Attenuated Intranasal Influenza Vaccine (LAIV) under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. If the PGD is used for supply the subsequent immediate self-administration or administration by another healthcare worker is outside the remit of this PGD and should only take place in well-defined local circumstances covered by protocols and training. Administration under this PGD must be directly by the named registered health professional. who has assessed the patient under the PGD.

This PGD template has been adopted by NoS for use across all 6 NoS Health Boards.

This PGD has been produced for NoS by				**Date Signed**
Doctor	Dr William Moore	Signature	William Moore	25/08/2022
Pharmacist	Liam Callaghan	Signature	L Coyle	11/08/2022
Nurse	Pauline Merchant	Signature		11/08/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	**Signature**	**Date Signed**
Lesley Coyle		22/09/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Professor Caroline Hiscox	C Hiscox	22/09/2022

Version 1.1 effective from 22nd September 2022 review date 31st July 2023

Clinical situation

Category	Description
Indication	Active immunisation against disease caused by influenza virus in line with Scottish Government seasonal influenza immunisation programme 2022/23.
Inclusion criteria	Valid consent has been given to receive the vaccine. Individuals identified in Scottish Government's seasonal influenza vaccination programme 2022/23 in the following groups: • individuals aged from 2 years to under 18 years in the clinical risk groups laid out in Scottish Government seasonal influenza immunisation programme letter • children aged 2 to 5 years of age on 1 September 2022 (born on or before 1 September 2020) not yet at school. • individuals of primary school age. • individuals at secondary school • young carers, defined as, a child or young person under the age of 18 carrying out significant caring tasks and assuming a level of responsibility for another person, which would normally be taken by an adult. • Those young people under 18 years of age eligible groups described in Scottish Government seasonal influenza immunisation programme letter
Exclusion criteria	Individuals who: • Are aged under 2 years. • Are aged 18 years and over unless attending secondary school – see below. • Have had a confirmed anaphylactic reaction to a previous dose of influenza vaccine. • Have had a confirmed anaphylactic reaction to any component of the vaccine including gelatin and gentamicin. Practitioners must check the marketing authorisation holder's summary of product characteristics (SPC) for details of vaccine components. • Have required admission to intensive care for a previous severe anaphylaxis to egg. JCVI has advised that children with an egg allergy – including those with previous anaphylaxis to egg – can be safely vaccinated with LAIV in any setting (including primary care and schools). • Have severe asthma or active wheezing including those: ○ with evidence of active wheezing in the previous 72 hours ○ with evidence of increased use of bronchodilators in the previous 72 hours ○ those who require regular oral steroids for maintenance of asthma control

Category	Description
	○ those who have previously required intensive care for asthma exacerbation • Are known to be clinically severely immunocompromised due to conditions or immunosuppressive therapy such as acute and chronic leukaemias; lymphoma; HIV infection not suppressed by antiretroviral therapy; cellular immune deficiencies; and high dose corticosteroids until at least three months after treatment has stopped including adults on more than 40mg prednisolone per day or 2mg/ kg/day in children under 20kg for more than one week, or adults on more than 20mg prednisolone per day or 1mg/kg/day in children under 20kg for more than 14 days. • Are currently being treated for a malignant disease with immunosuppressive chemotherapy or radiotherapy, or those who have terminated such treatment within at least the last 6 months. • Have received a solid organ transplant and are currently on or have received in the last 6 months' immunosuppressive treatment. • Have received an allogenic (cells from a donor) stem cell transplant in the past 24 months and only then if they are demonstrated not to have on-going immunosuppression or graft versus host disease (GVHD). • Have received an autologous (using their own stem cells) haematopoietic stem cell transplant in the past 24 months and only then if they are in remission. • Are receiving or have received in the past 12 months immunosuppressive biological therapy (e.g. anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab) unless otherwise directed by a specialist. • Are receiving or have received in the past 3 months high dose non-biological oral immune modulating drugs (e.g. methotrexate dose greater than 25mg per week in adults or 15mg/m2 in children, azathioprine dose greater than 3.0mg/kg/day or 6-mercaptopurine dose greater than 1.5mg/kg/day), for the treatment of rheumatoid arthritis, psoriasis, polymyositis, sarcoidosis, inflammatory bowel disease and other conditions. • Are known to be a close contact of a very severely immunocompromised person (e.g. bone marrow transplant recipient). • Are known to be taking salicylate therapy (other than for topical treatment of localised conditions). • Are known to be pregnant. • Are known to be breastfeeding. • Are currently taking or are within 48 hours of cessation of influenza antiviral agents. • Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).

Category	Description
Cautions/need for further advice/ circumstances when further advice should be sought from a doctor	The Green Book advises that there are very few individuals who cannot receive Live Attenuated Intranasal Influenza Vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation coordinator or health protection team. There is a theoretical potential for transmission of live attenuated influenza virus in LAIV to very severely immunocompromised contacts (e.g. bone marrow transplant patients requiring isolation) for one to two weeks following vaccination. Where close contact with immunocompromised patients (e.g. household members) is likely or unavoidable, an appropriate quadrivalent inactivated influenza vaccine should be considered. Not all brands of quadrivalent inactivated vaccine are recommended for use in children. There are no data on the effectiveness of LAIV when given to children with a heavily blocked or runny nose (rhinitis) attributable to infection or allergy. As heavy nasal congestion might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration until resolution of the nasal congestion or an appropriate quadrivalent inactivated influenza vaccine should be considered. Long term stable low dose corticosteroid therapy, either alone or in combination with low dose non-biological oral immune modulating drugs (e.g. methotrexate 25mg per week in adults or up to 15mg/m2 in children, azathioprine 3.0mg/kg/day or 6-mercaptopurine 1.5mg/kg/day), are not considered sufficiently immunosuppressive and these patients can receive live vaccines. Children with cochlear implants can be given LAIV safely although ideally not in the week prior to implant surgery or for two weeks afterwards, or if there is evidence of on-going cerebrospinal fluid leak.
Action if excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in accordance with local procedures Inform or refer to the clinician in charge at the clinic or GP as appropriate. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. In case of postponement due to acute wheezing/increased use of bronchodilators offer/arrange for a suitable quadrivalent inactivated vaccine to avoid a delay in protection.

Category	Description
	In case of exclusion due to regular oral steroids for maintenance of asthma control or having previously required intensive care for asthma due to limited safety data in these children advice from the child's specialist should be sought on the vaccine and circumstances under which it could be given. In case of exclusion as result of immunosuppression, pregnancy or salicylate therapy (other than for topical treatment of localised conditions), consider use of an appropriate quadrivalent inactivated influenza vaccine.
Action if patient declines	Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine. Document advice given and decision reached. inform or refer to clinician in charge.

Description of treatment

Category	Description
Name of medicine **Form/strength**	Live attenuated intranasal influenza vaccine (LAIV) Nasal spray, suspension in a prefilled nasal applicator
Route of administration	Nasal administration only. LAIV must not be injected. The patient can breathe normally while the vaccine is being administered – there is no need to actively inhale or sniff. If the PGD is used for supply the subsequent immediate self-administration or administration by another healthcare worker is outside the remit of this PGD and should only take place in well-defined local circumstances covered by protocols and training. Administration under this PGD must be directly by the named registered health professional.
Dosage	0.2mL (administered as 0.1mL per nostril). LAIV is administered as a divided dose in both nostrils.

Category	Description
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.
Duration of treatment	See Frequency section
Maximum or minimum treatment period	See Frequency section
Quantity to supply/administer	0.2mL (administered as 0.1mL per nostril).
▼ black triangle medicines	No
Legal category	Prescription Only Medicine (POM)
Is the use out with the SmPC?	Yes. The SmPC states that in children who have not previously been immunised against influenza, a second dose should be given after an interval of at least four weeks. This is superseded by the Green Book recommendation to give a single dose of LAIV to children not in a clinical at risk group. LAIV is licensed for administration to children and adolescents from 24 months to less than 18 years of age. It may be administered under this PGD to those individuals aged 18 years in secondary school accordance with the Scottish Government seasonal influenza immunisation programme 2022/23. Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines or HPS vaccine incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration or supply under this PGD is allowed.

Category	Description
Storage requirements	Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. NHS board guidance on storage and handling of vaccines should be observed. Before use, the vaccine may be taken out of the refrigerator once for a maximum period of 12 hours at a temperature not above 25°C. Stability data indicate that the vaccine components are stable for 12 hours when stored at temperatures from 8°C to 25°C. At the end of this period, Fluenz Tetra should be used immediately or discarded. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal.
Additional information	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. The patient 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 patient sneezes or blows their nose following administration. LAIV can be given at the same time as other vaccines including COVID-19 vaccine and live vaccines. No specific intervals need to be observed between LAIV and other live vaccines.

Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	Nasal congestion/runny nose, reduced appetite, weakness and headache are common adverse reactions following administration of LAIV. It is uncommon, but some children may experience a nosebleed following administration of LAIV. For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

Category	Description
	In the event of a severe adverse reaction individual should be advised to seek medical advice.
Reporting procedure for adverse reactions	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 in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.
Advice to patient or carer including written information	Written information to be given to individuals: • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Supply immunisation promotional material as appropriate. Individual advice / follow up treatment • Inform the individual/carer of possible side effects and their management. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://www.mhra.gov.uk/yellowcard • When applicable, advise individual/parent/carer when the subsequent dose is due. • Give general advice relating to good hygiene practice to prevent the spread of germs – always have tissues to hand, use a clean tissue to cover your mouth and nose when you cough and/or sneeze, bin any tissue after one use, wash your hands with soap and hot water or a sanitiser gel often.
Observation following vaccination	Following immunisation patients remain under observation in line with NHS board policy.
Follow up	If appropriate remind parents/guardian that a further dose will be required to complete the course.
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given.

Category	Description
	Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to supply or administer this vaccine • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • 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.
Specialist competencies or qualifications	Persons must only work under this PGD where they are competent to do so. All persons operating this PGD: • must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it • must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information, • must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent • must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine • must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy

Category	Description
	Employer The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD. As a minimum, competence requirements stipulated in the PGD must be adhered to.
Continuing education and training	All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

Audit trail

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability for vaccine • whether the vaccine was administered or supplied for immediate administration by another person • name of person that administered the vaccine • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • batch number • where possible expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken

Name	Description
	• administered under PGD Records should be kept line with local procedures. Local policy should be followed to encourage information sharing with the individual's General Practice. All records should be clear, legible and contemporaneous and in an easily retrievable format.

Additional references

Name	Description
Additional references	Practitioners operating the PGD must be familiar with: • Immunisation against Infectious Disease [Green Book] • Immunisation against Infectious Disease [Green Book] chapter 19 • Current edition of British National Formulary (BNF) and BNF for children • Marketing authorisation holder's Summary of Product Characteristics • Educational resources for registered professionals produced by National Education for Scotland • All relevant Scottish Government advice including the relevant CMO letter(s) • Professional Guidance on the Administration of Medicines in Healthcare Settings 2019 • Professional Guidance on the Safe and Secure Handling of Medicines

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

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Health Board, Area Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

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 (Version 1.1 – Valid from 22nd September 2022)

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction. **PGDs do not remove inherent professional obligations or accountability.**

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

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

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
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 (Version 1.1 – Valid from 22nd September 2022)
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Version history

Version	Date	Summary of changes
V1.0	01.08.2022	The following changes from the PGD used in 2021/22 have been made: • Indication section updated for dates for 2022/23 season • Inclusion criteria section updated for dates for 2022/23 season
V1.1	22 September 2022	• Exclusion section wording on those with HIV updated to align with wording in Green Book chapter 19 • Cautions section updated to align with wording in Green Book chapter 19 for those with cochlear implants