



This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

## **Patient Group Direction (PGD)**

For the administration of

**Live Attenuated Influenza Vaccine (LAIV) nasal spray suspension  
(Fluenz Tetra)**

By registered health care professionals for

**Children and adolescents from 2 years to under 18 years of age in  
accordance with the national flu immunisation programme**

**Throughout the Manx Care and those contracted by the Manx Care where appropriate within  
practice**

**PGD NUMBER 160**

## 1. Change History

Version number	Change Details	Date
Final version	New PHE Fluenz PGD	01/09/2013
Final version – revised	See earlier version of this PGD for change details.	09/09/2013
V02.00	See earlier version of this PGD for change details.	11/08/2015
V03.00	See earlier version of this PGD for change details.	20/10/2015
V04.00	See earlier version of this PGD for change details.	22/06/2016
V05.00	See earlier version of this PGD for change details.	04/07/2017
V06.00	See earlier version of this PGD for change details.	17/08/2017
V07.00	See earlier version of this PGD for change details.	08/06/2018
V08.00	<p>PHE LAIV PGD amended to:</p> <ul style="list-style-type: none"> <li>include the 2019/20 influenza programme eligible cohorts, with the addition of children of appropriate age for school year 6</li> <li>remove the exclusion of individuals on high dose inhaled corticosteroids and replace with the exclusion of individuals who require oral steroid for the maintenance of asthma control or have previously required intensive care for an asthma exacerbation, in accordance with updated recommendations from JCVI and in Chapter 19 of ‘The Green Book’</li> <li>include reference to the Directed Enhanced Service and offer to morbidly obese adults from 16 years of age</li> <li>include minor rewording, layout and formatting changes to remove duplication and for clarity and consistency with other PHE PGD templates</li> </ul>	08/05/2019
V09.00	<p>PHE LAIV PGD amended to:</p> <ul style="list-style-type: none"> <li>extend the characteristics of staff to include all registered practitioners legally able to work under PGD</li> <li>include the 2020/21 influenza programme eligible DOB cohorts and household contacts of those on the Covid-19 Shielded Patient List</li> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	16/07/2020
V10.00	<p>PHE LAIV PGD amended to:</p> <ul style="list-style-type: none"> <li>include the 2020/21 influenza programme eligible cohorts</li> </ul>	28/07/2021

## 2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

## 3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

## 4. PGD authorisation

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

## 5. PGD adoption by the provider

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job title and organisation	Signature	Date	Applicable or not applicable to area

## 6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the [NICE PGD competency framework for health professionals using PGDs](#)

	Requirements of registered Healthcare professionals working under the PGD
<b>Qualifications and professional registration</b>	<p>Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy</p> <p>Additionally practitioners:</p> <ul style="list-style-type: none"> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (<u>'The Green Book'</u>), and national and local immunisation programmes</li> <li>• 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 Immunisation Training</u>. For further information on immunisation training during the COVID-19 pandemic see <u>Guidance on immunisation training during the COVID-19 pandemic</u></li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>• must be competent in the handling and storage of vaccines, and management of the 'cold chain'</li> <li>• must be competent in the recognition and management of anaphylaxis</li> </ul> <p>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).</p>

<b>Initial training</b>	<ul style="list-style-type: none"> <li>• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria</li> <li>• Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD</li> <li>• Local training in the use of PGD's</li> </ul>
<b>Competency assessment</b>	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
<b>Ongoing training and competency</b>	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

## 7. Clinical Conditions

<b>Clinical condition or situation to which this PGD applies</b>	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 <u>Chapter 19</u> of Immunisation Against Infectious Disease: 'The Green Book' and <u>annual flu letter(s)</u> .
<b>Inclusion criteria</b> (continued)	<p>Individuals eligible for vaccination with LAIV in accordance with national recommendations for 2021/22 including:</p> <ul style="list-style-type: none"> <li>• all children aged 2 to 15 (but not 16 years or older) on 31 August 2021 <ul style="list-style-type: none"> <li>○ all those aged 2 and 3 years on 31 August 2021 (with a date of birth on or after 1 September 2017 and on or before 31 August 2019)</li> <li>○ all primary school-aged children in Reception Year to Year 6 (aged 4 to 10 years old on 31 August 2021) regardless of whether they attend school</li> <li>○ all secondary school-aged children in Years 7 to Year 11 (aged 11 to 15 years old on 31 August 2021) regardless of whether they attend school</li> </ul> <p>some school aged children might be outside of the age ranges outlined in the above paragraphs (for example, if a child has been accelerated or held back a year). It is acceptable to offer and deliver immunisations to these children with their class peers under this PGD</p> </li> <li>• children and adolescents from 2 years to under 18 years of age who are in a clinical risk group category listed in <u>Chapter 19</u> of 'The Green Book' such as: <ul style="list-style-type: none"> <li>○ chronic (long-term) respiratory disease, such as asthma (that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission), chronic obstructive pulmonary disease</li> </ul> </li> </ul>

<p><b>Inclusion criteria</b> (continued)</p>	<p>(COPD) or bronchitis</p> <ul style="list-style-type: none"> <li>○ chronic heart disease, such as heart failure</li> <li>○ chronic kidney disease at stage 3, 4 or 5</li> <li>○ chronic liver disease</li> <li>○ chronic neurological disease, such as Parkinson’s disease or motor neurone disease</li> <li>○ learning disability</li> <li>○ diabetes</li> <li>○ asplenia or splenic dysfunction</li> <li>○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)</li> <li>○ morbidly obese adults (aged from 16 years) with a BMI <math>\geq</math> 40kg/m<sup>2</sup></li> </ul> <ul style="list-style-type: none"> <li>● children and adolescents from 2 years to under 18 years of age who are close contacts of immunocompromised individuals, such as individuals who expect to share living accommodation on most days over the winter and therefore for whom continuing close contact is unavoidable (Note: contacts of very severely immunocompromised individuals should receive inactivated influenza vaccine and not LAIV, see Inactivated Influenza PGD)</li> <li>● 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</li> <li>● health and social care staff, from 16 years to under 18 years of age, employed by a registered residential care or nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable patients or clients who are at increased risk from exposure to influenza</li> <li>● health and care staff, from 16 years to under 18 years of age, employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable patients or clients who are at increased risk from exposure to influenza</li> <li>● health and social care workers, from 16 years to under 18 years of age, employed through Direct Payments (personal budgets) and/or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to patients and service users</li> </ul>
<p><b>Exclusion criteria<sup>1</sup></b> (continued)</p>	<p>LAIV must not be given under this PGD to:</p> <ul style="list-style-type: none"> <li>● individuals for whom no valid consent has been received (see <a href="#">Chapter 2</a> of ‘<a href="#">The Green Book</a>’)</li> <li>● children and infants under 2 years of age</li> <li>● adults aged 18 years and over</li> <li>● individuals who have received a dose of influenza vaccine for the current season, unless they are individuals aged 2 to less</li> </ul>

<sup>1</sup> 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.

<p><b>Exclusion criteria</b> (continued)</p>	<p>than 9 years in a clinical risk group category listed in <u>Chapter 19</u> of the 'The Green Book' who should, in the first season they are vaccinated against influenza, receive a second dose of LAIV at least 4 weeks after the first dose</p> <ul style="list-style-type: none"> <li>• individuals with a confirmed anaphylactic reaction to a previous dose of influenza vaccine</li> <li>• 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 <u>Additional information</u> section)</li> <li>• individuals with severe anaphylaxis to egg which has previously required intensive care</li> <li>• individuals with severe asthma who have previously required intensive care for asthma exacerbation or who require regular oral steroids for the maintenance of asthma control, for example children who are currently taking oral steroids or who have been prescribed oral steroids in the past 14 days, unless LAIV is advised by their respiratory specialist</li> <li>• 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</li> <li>• individuals with unrepaired craniofacial malformations</li> <li>• pregnant individuals, see the PHE Inactivated Influenza PGD Note: There is no need to specifically test eligible girls for pregnancy or to advise avoidance of pregnancy in those who have been recently vaccinated.</li> <li>• individuals who are clinically severely immunodeficient due to a condition or immunosuppressive therapy such as: <ul style="list-style-type: none"> <li>○ acute and chronic leukaemias</li> <li>○ lymphoma</li> <li>○ HIV infection not on highly active antiretroviral therapy (HAART)</li> <li>○ cellular immune deficiencies</li> <li>○ high dose corticosteroids (prednisolone at least 2mg/kg/day for a week or 1mg/kg/day for a month or equivalent)</li> </ul> see the PHE Inactivated Influenza PGD </li> <li>• individuals for whom close contact with very severely immunocompromised patients (for instance, bone marrow transplant patients requiring isolation) is likely or unavoidable (for example, household members), see the PHE Inactivated Influenza PGD</li> <li>• individuals offered vaccination as part of an employer's occupational health scheme</li> </ul> <p><b>Temporary exclusion</b> LAIV administration should be postponed for individuals who:</p>
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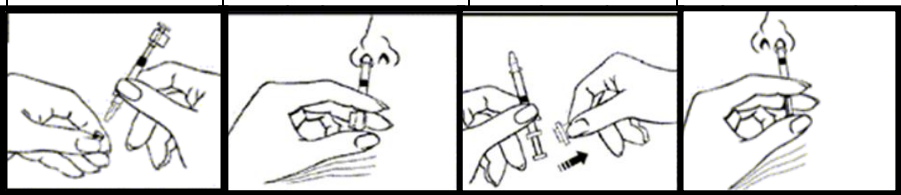
<b>Exclusion criteria</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>• are suffering from acute febrile illness until completely recovered</li> <li>• are suffering from heavy nasal congestion which may impede delivery of the vaccine to the nasopharyngeal mucosa until congestion has resolved</li> <li>• 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 be taken if the patient is excluded</u></li> <li>• received treatment with influenza antiviral agents in the last 48 hours until 48 hours following the cessation of treatment with influenza antiviral agents</li> </ul>
<b>Cautions (including any relevant action to be taken)</b>	<p>Individuals who have immunosuppression and HIV infection may not make a full antibody response to the vaccine.</p>
<b>Arrangements for referral for medical advice</b>	<p>Patient should be referred to a more experienced clinical practitioner for further assessment</p>
<b>Action to be taken if patient excluded</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>• Patient should be referred to a more experienced clinical practitioner for further assessment</li> <li>• Children and adolescents who are eligible for influenza vaccination but for whom LAIV is contraindicated (or is otherwise unsuitable, for instance due to the route or non-acceptance of porcine gelatine content) should be considered for an appropriate alternative inactivated influenza vaccine, see the PHE Inactivated Influenza PGD</li> <li>• Children and adolescents with a history of severe anaphylaxis to egg which has required intensive care should be referred to specialists for immunisation in hospital. LAIV remains the preferred vaccine for this group and the intranasal route is less likely to cause systemic reactions. Egg-allergic adults and children over age two years with egg allergy can alternatively be given the quadrivalent inactivated egg-free vaccine, Flucelvax® Tetra ▼, which is licensed for use in this age group (see Inactivated Influenza PGD). JCVI has advised that, except for those with severe anaphylaxis to egg which has previously required intensive care, children with an egg allergy can be safely vaccinated with LAIV in any setting (including primary care and schools)</li> <li>• Individuals who have previously required intensive care for asthma exacerbation or who require regular oral steroids for the maintenance of asthma control should only be given LAIV on the advice of their specialist. As these children are a defined risk group for influenza, those who cannot receive LAIV should receive an inactivated influenza vaccine, see the PHE Inactivated Influenza PGD</li> <li>• All pregnant individuals should be offered inactivated influenza vaccine unless otherwise contraindicated, see the PHE Inactivated Influenza PGD</li> </ul>



<p><b>Action to be taken if patient excluded</b> (continued)</p>	<ul style="list-style-type: none"> <li>• Vaccination with inactivated influenza vaccine should be considered for immunosuppressed individuals excluded from receiving LAIV and those who are contacts of individuals who are very severely immunocompromised, see the PHE Inactivated Influenza PGD</li> <li>• Individuals temporarily excluded may be offered LAIV at a later date. In case of postponement arrange a future date for vaccination</li> <li>• Individuals who have a history of active wheezing in the past 72 hours or those who have increased their use of bronchodilators in the previous 72 hours whose condition has not improved after a further 72 hours should be offered an inactivated influenza vaccine to avoid delaying protection in this high-risk group, see the PHE Inactivated Influenza PGD</li> <li>• Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or individual's clinician as required</li> <li>• The risk to the individual of not being immunised must be taken into account</li> <li>• Document the reason for exclusion and any action taken in the individual's clinical records.</li> <li>• Inform or refer to the GP or a prescriber as appropriate</li> </ul>
<p><b>Action to be taken if patient declines treatment</b></p>	<ul style="list-style-type: none"> <li>• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment</li> <li>• This information must be documented in the patients' health records</li> <li>• Any patient who declines care must have demonstrated capacity to do so</li> <li>• Where appropriate care should be escalated</li> <li>• Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration</li> </ul>

## 8. Details of the medicine

<b>Name, form and strength of medicine</b>	Live attenuated influenza vaccine nasal spray suspension (0.2 ml) (Influenza vaccine, live attenuated), for instance: <ul style="list-style-type: none"> <li>• Fluenz Tetra nasal spray suspension (0.2 ml) in pre-filled nasal applicator (influenza vaccine, live attenuated)</li> </ul>
<b>Legal category</b>	Prescription only medicine (POM)
<b>Black triangle ▼</b>	Yes
<b>Indicate any <u>off-label use</u> (if relevant)</b>	<p>Fluenz Tetra SPC states “For children who have not previously been vaccinated against seasonal influenza, a second dose should be given after an interval of at least 4 weeks.” However, JCVI has advised that children who are not in a clinical risk group, only require a single dose of LAIV irrespective of whether they have received influenza vaccine previously.</p> <p>Fluenz Tetra is contraindicated in children and adolescents receiving salicylate therapy because of the association of Reye’s syndrome with salicylates and wild-type influenza infection. However, LAIV may be administered off-label to individuals receiving topical salicylate treatment for the management of localised conditions, in accordance with <u>Chapter 19</u> of the ‘<u>The Green Book</u>’.</p> <p>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).</p> <p>Vaccine 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>PHE Vaccine Incident Guidance</u>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
<b>Route/method of administration</b>	<ul style="list-style-type: none"> <li>• LAIV is for intranasal application only</li> <li>• Single application in each nostril of 0.1ml</li> <li>• The individual can breathe normally during vaccine administration and there is no need to actively inhale or sniff</li> <li>• The SPC provides further guidance on administration: <a href="http://www.medicines.org.uk/emc/medicine/29112">http://www.medicines.org.uk/emc/medicine/29112</a></li> </ul>

	<p><b>Instructions for administration</b></p>  <p>dose-divider      possible</p>
<p><b>Dose and frequency</b></p>	<p>Single dose of 0.2ml of LAIV administered as 0.1ml in each nostril.</p> <p><b>Children in clinical risk groups</b></p> <ul style="list-style-type: none"> <li>• Children aged 2 to less than 9 years who are in a clinical risk group category listed in <u>Chapter 19</u> of the '<u>The Green Book</u>' and who have not received influenza vaccine before, should receive a second dose of LAIV at least 4 weeks after the first dose</li> <li>• Second dose of 0.2ml of LAIV administered as 0.1ml in each nostril</li> </ul>
<p><b>Quantity to be administered</b></p>	<p>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.</p> <p>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.</p> <p><b>Children aged 2 years to less than 9 years old in a clinical risk category and receiving influenza immunisation for the first time</b></p>
<p><b>Maximum or minimum treatment period</b></p>	<p>This dose (0.2ml) should be repeated after a 4-week interval</p>
<p><b>Storage</b></p>	<ul style="list-style-type: none"> <li>• Store at +2°C to +8°C.</li> <li>• Store in original packaging to protect from light.</li> <li>• Do not freeze.</li> <li>• Before use, the vaccine may be removed from the cold-chain, without being replaced, for a maximum period of 12 hours at a temperature not above 25°C. If the vaccine has not been used after this 12-hour period, it should be disposed of.</li> <li>• 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, refer to <u>PHE Vaccine Incident Guidance</u></li> </ul>
<p><b>Adverse effects</b></p>	<p>The most common adverse reactions observed after administration of LAIV are decreased appetite, headache, nasal congestion, rhinorrhoea, malaise. Less common reactions include myalgia and pyrexia and uncommon reactions include hypersensitivity reactions,</p>

	<p>epistaxis and rash.</p> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic medicines compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p> <p><b>Reporting procedure of adverse reactions</b></p> <p>Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a> or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.</p>
<b>Records to be kept</b>	<p>The administration of any medication given under a PGD must be recorded within the patients' medical records</p> <p>Please see Appendix C for more details.</p>

## 9. Patient information

<b>Verbal/Written information to be given to patient or carer</b>	<ul style="list-style-type: none"> <li>• Verbal information must be given to patients and or carers for all medication being administered under a PGD</li> <li>• Where medication is being supplied under a PGD, written patient information leaflet must also be supplied</li> <li>• A patient information leaflet is available on request</li> </ul>
<b>Follow-up advice to be given to patient or carer</b> <i>(continued)</i>	<ul style="list-style-type: none"> <li>• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately</li> <li>• When administration is postponed advise the individual/carer/parent when to return for vaccination</li> <li>• Inform the individual/parent/carer of possible side effects and their management</li> <li>• The individual/parent/carer should be advised when to seek medical advice in the event of a severe adverse reaction</li> <li>• When applicable, advise the individual/parent/carer when the subsequent dose is due</li> <li>• The individual/parent/carer should be informed that LAIV has the theoretical potential for transmission to immunocompromised contacts. Vaccine recipients should attempt to avoid, whenever possible, close association with very severely immunocompromised individuals (such as bone marrow transplant recipients requiring isolation) for 1-2 weeks following vaccination</li> <li>• When administration is postponed advise the individual/parent/carer when to return for vaccination.</li> </ul>

## 10. Appendix A

### References

1. British National Formulary (BNF) available online: <https://bnf.nice.org.uk>
2. Nursing and Midwifery (2018) "The code" available online: <https://www.nmc.org.uk>
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: <https://www.medicines.org.uk>

### LAIV

- Immunisation Against Infectious Disease: The Green Book. Chapter 19, Updated 29 October 2020.  
<https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19>
- Collection: Annual Flu Programme. Updated 29 July 2021  
<https://www.gov.uk/government/collections/annual-flu-programme>
- The national flu immunisation programme 2021 to 2022: supporting letter. Published 17 July 2021.  
<https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan>
- GP Contract 2021/22: NHS England and NHS Improvement.  
<https://www.england.nhs.uk/gp/investment/gp-contract/>
- Summary of Product Characteristics for Fluenz Tetra. AstraZeneca UK Ltd. 8 March 2021.  
<https://www.medicines.org.uk/emc/product/3296>
- PHE Inactivated Influenza Vaccine PGD.  
<https://www.gov.uk/government/publications/intramuscular-inactivated-influenza-vaccine-patient-group-direction-pgd-template>
- Flu Vaccinations: Supporting people with learning disabilities. 25 September 2018.  
<https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities>

### General

- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. <https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste>
- Immunisation Against Infectious Disease: The Green Book. Chapter 2. Updated 18 June 2021.  
<https://www.gov.uk/government/publications/consent-the-green-book-chapter-2>
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. <https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners>
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <https://www.nice.org.uk/guidance/mpg2>
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. March 2017.  
<https://www.nice.org.uk/guidance/mpg2/resources>
- Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017.  
<https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them>

- PHE Guidance on immunisation training during the COVID-19 pandemic. 26 June 2020. <https://www.gov.uk/government/publications/immunisation-training-guidance-during-the-covid-19-pandemic/guidance-on-immunisation-training-during-the-covid-19-pandemic>
- PHE Immunisation Collection. <https://www.gov.uk/government/collections/immunisation>
- PHE Vaccine Incident Guidance <https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors>

## 11. Appendix B

Health professionals agreed to practice
<ul style="list-style-type: none"> <li>• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor</li> <li>• A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves</li> </ul>

## 12. Appendix C

<p><b>Special considerations/ additional information</b></p>	<ul style="list-style-type: none"> <li>• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination</li> <li>• 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</li> <li>• 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</li> <li>• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and easy access to a telephone</li> <li>• For children under the age of 16 years, those assessed as Gillick competent can self-consent (see DH <a href="#">Reference guide to consent for examination or treatment</a>)</li> <li>• 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</li> <li>• 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)</li> <li>• LAIV is not contraindicated for use in children or adolescents with stable HIV infection receiving antiretroviral therapy; or who are receiving topical corticosteroids, inhaled corticosteroids, low-dose</li> </ul>
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	<p>systemic corticosteroids or those receiving corticosteroids as replacement therapy (such as for adrenal insufficiency) or low-dose immunosuppressive therapy. This PGD may be used for these individuals</p> <ul style="list-style-type: none"> <li>• Individuals with learning disabilities may require reasonable adjustments to support vaccination (see <a href="https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities">https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities</a>). A PSD may be required.</li> <li>• If the PGD is used for supply only for subsequent administration by an appropriately trained HCSW, the registered practitioner named in Section 7 of this PGD must supply the vaccine to the individual/carer. The HCSW cannot supply the medicine</li> </ul> <p><b>Exposure of healthcare professionals</b></p> <ul style="list-style-type: none"> <li>• 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</li> </ul>
<b>Disposal</b>	<p>Equipment used for immunisation, including discharged or partially discharged vaccines in an applicator, should be disposed of safely, as medicinally-contaminated clinical waste for incineration, in a yellow UN-approved waste receptacle (this is usually a sharps box), according to local authority regulations and guidance in the <a href="#">technical memorandum 07-01</a> (Department of Health, 2013).</p>
<b>Drug interactions</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• LAIV should be delayed until 48 hours following the cessation of treatment with influenza antiviral agents.</li> <li>• Administration of influenza antiviral agents within the 2 weeks following administration of LAIV may adversely affect the effectiveness of the vaccine.</li> <li>• 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.</li> <li>• LAIV can be given at the same time as other live or inactivated vaccines. Although it was previously recommended that, where vaccines cannot be administered simultaneously, a 4-week interval should be observed between live viral vaccines, JCVI have advised that no specific intervals need to be observed between LAIV and other live vaccines.</li> <li>• A detailed list of drug interactions is available in the SPC, which is available from the electronic medicines compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></li> </ul>

<b>Supplies</b>	<ul style="list-style-type: none"> <li>• LAIV has been purchased centrally for children. These vaccines should be ordered as per the usual mechanisms for the routine childhood immunisation programme</li> <li>• Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book <a href="#">Chapter 3</a>)</li> </ul>
<b>Records</b>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given</li> <li>• name of individual, address, date of birth and GP with whom the individual is registered</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via PGD</li> </ul> <ul style="list-style-type: none"> <li>• Records should be signed and dated (or a password-controlled immuniser's record on e-records)</li> <li>• All records should be clear, legible and contemporaneous.</li> <li>• This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed</li> <li>• The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement</li> <li>• A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy</li> <li>• 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.</li> </ul>