



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

### **Inactivated influenza vaccine**

By registered health care professionals for

### **individuals in accordance with the national influenza immunisation programme**

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

## **PGD NUMBER 162**

## 1. Change History

Version number	Change Details	Date
V01.00 – V06.00	See earlier version of this PGD for change details.	18/08/2015 – 10/08/2018
V07.00	<p>PHE IM Influenza PGD amended to:</p> <ul style="list-style-type: none"> <li>remove inclusion criteria relating to the immunisation of health and social care workers as part of an organisation’s occupational health obligation and refer to the national written instruction template</li> <li>include vaccines for the 2019/20 season, including cell-based quadrivalent influenza vaccine (QIVc)</li> <li>update cautions for egg allergy and include use of QIVc which is egg-free</li> <li>include reference to the Directed Enhanced Service and offer to morbidly obese adults from 16 years of age</li> <li>include reference to the Flu Vaccinations: Supporting people with learning disabilities guidance from PHE</li> </ul>	08/05/2019
V08.00	<p>PHE IM Influenza 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 household contacts of those on the NHS Shielded Patient List, health and social care workers employed through Direct Payments or Personal Health Budgets and, subject to vaccine supply, extension of the programme to individuals from 50 years of age and children in routine age cohorts unable to receive LAIV</li> <li>update the table of recommended inactivated influenza vaccines for the 2020/21 season</li> <li>update supplies section</li> <li>remove reference to Flud<sup>®</sup> brand which will not be supplied to UK this season and remove black triangle from Fluarix<sup>®</sup> Tetra</li> <li>remove reference to barium sulphate which is no longer listed in the adjuvanted trivalent influenza influenza vaccine SPC as a residue of the manufacturing process</li> <li>update additional information section</li> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs</li> </ul>	24/08/2020
V09.00	<p>PHE Inactivated Influenza PGD amended to:</p> <ul style="list-style-type: none"> <li>include eligible cohorts for the 2021/22 season</li> <li>include the inactivated influenza vaccines for the 2021/22 season</li> <li>include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs</li> </ul>	23/07/2021
V10.00	<p>Inactivated Influenza PGD amended to:</p> <ul style="list-style-type: none"> <li>include the inactivated influenza vaccines for the 2022/23 season</li> <li>include minor rewording, layout and formatting changes</li> <li>Addition of the prison into the inclusion criteria</li> </ul>	14/07/2022

## 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)	N/A	N/A	N/A

## 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 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> <i>(continued)</i>	<p>Registered healthcare professionals, working within or contracted by Manx Care, GP practices 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 ('The Green Book'), 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></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> <li>• should fulfil any additional requirements defined by local policy</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> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and NHS Improvement and other sources of medicines information.</p>

<b>Qualifications and professional registration</b> <i>(continued)</i>	<p>Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p> <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>• Training in the use of PGD's</li> </ul>
<b>Competency assessment</b>	<p>Staff will be assessed on their knowledge of drugs and clinical assessment as part of the competency framework for registered health professionals using PGD's</p>
<b>Ongoing training and competency</b>	<p>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 annually.</p>

## 7. Clinical Conditions

<b>Clinical condition or situation to which this PGD applies</b>	<p>Inactivated influenza vaccine is indicated for the active immunisation of individuals for the prevention of influenza infection, in accordance with the national immunisation programme and recommendations given in <u>Chapter 19</u> of the Immunisation Against Infectious Disease: the 'Green Book', <u>annual flu letter(s)</u> and subsequent correspondence/publications from PHE and/or NHS England and NHS Improvement.</p> <p>Note: This PGD covers NHS commissioned services. This PGD does not cover the provision of occupational health schemes or peer-to-peer influenza immunisation (See NHS Specialist Pharmacy Service '<u>Written instruction template for the administration of inactivated seasonal influenza vaccine as part of an occupational health scheme, which may include peer-to-peer immunisation</u>' or the <u>National protocol for inactivated influenza vaccine</u>)</p>
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<p><b>Inclusion criteria</b> (continued)</p>	<p>In 2022/23, influenza vaccine should be offered to the following groups:</p> <ul style="list-style-type: none"> <li>○ healthy people aged 50 years or over (including those becoming age 50 years by 31 March 2023)</li> <li>○ people aged from 6 months to under 50 years in a clinical risk group category listed in <a href="#">Chapter 19</a> 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 (COPD) or bronchitis</li> <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 and adrenal insufficiency</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 40\text{kg/m}^2</math></li> <li>○ all pregnant women (including those women who become pregnant during the influenza season)</li> <li>○ household contacts of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and, therefore, for whom continuing close contact is unavoidable</li> <li>○ people living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, young offender institutions, university halls of residence or boarding schools</li> <li>○ residents in the prison</li> <li>○ people 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, 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, employed by a voluntary managed hospice provider, who are directly involved in the care of</li> </ul> </li> </ul>
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<b>Inclusion criteria</b> <i>(continued)</i>	<p>vulnerable patients or clients who are at increased risk from exposure to influenza</p> <ul style="list-style-type: none"> <li>○ locum GPs (see <a href="#">Additional Information</a>)</li> <li>○ children eligible for the Routine Childhood Seasonal Influenza Vaccination Programme (aged 2 years to 15 years on 31 August 2021) for whom live attenuated influenza vaccine (LAIV) is contraindicated (or is otherwise unsuitable, for instance due to the route or non-acceptance of porcine gelatine content)</li> </ul>
<b>Exclusion criteria</b> <sup>1</sup>	<p>Individuals for whom no valid consent has been received (for further information on consent see <a href="#">Chapter 2</a> of '<a href="#">The Green Book</a>')</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are less than 6 months of age</li> <li>• are aged 2 years to under 18 years for whom live attenuated influenza vaccine (LAIV) is NOT contraindicated (or not otherwise unsuitable, for instance due to the route or non-acceptance of porcine gelatine content) and is available. Note: LAIV should be given to those aged 2 to under 18 years in preference to inactivated influenza vaccine where possible, see LAIV PGD.</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of the vaccine</li> <li>• have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process<sup>2</sup> (other than ovalbumin – see <a href="#">Cautions</a>)</li> <li>• have received a complete dose of the recommended influenza vaccine for the current season, unless they are individuals aged 6 months to less than 9 years in a clinical risk group category listed in <a href="#">Chapter 19</a> of the 'Green Book' who should, in the first season they are vaccinated against influenza, receive a second dose of an appropriate influenza vaccine at least 4 weeks after the first dose</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</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

<sup>2</sup> Residues from the manufacturing process may include beta-propiolactone, cetyltrimethylammonium bromide (CTAB), formaldehyde, gentamicin, hydrocortisone, kanamycin, neomycin, octoxinol-9, octylphenol ethoxylate, polysorbate 80, sodium deoxycholate. Check the vaccine products SPC for details.

<p><b>Cautions (including any relevant action to be taken)</b></p>	<p>Individuals with a bleeding disorder may develop a haematoma at the injection site (see <u>Route of Administration</u>).</p> <p>Individuals with a severe anaphylaxis to egg which has previously required intensive care can be immunised in any setting using an egg-free vaccine, for instance QIVc or QIVr. Individuals with less severe egg allergy can be immunised in any setting using an egg-free vaccine or an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to 0.06 micrograms for 0.5 ml dose). For details of the influenza vaccines available for the 2022 to 2023 season and their ovalbumin content see <u>All influenza vaccines marketed in the UK for the 2022 to 2023 season</u>  <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1068455/UKHSA-2022-ovalalbumin-table-2022-2023.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1068455/UKHSA-2022-ovalalbumin-table-2022-2023.pdf</a></p> <ul style="list-style-type: none"> <li>• 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</li> </ul>
<p><b>Arrangements for referral for medical advice</b></p>	<p>Patient should be referred to a more experienced clinical practitioner for further assessment</p>
<p><b>Action to be taken if patient excluded</b> (continued)</p>	<ul style="list-style-type: none"> <li>• Patient should be referred to a more experienced clinical practitioner for further assessment</li> <li>• 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, or a PSD obtained for immunisation</li> <li>• Individuals under 2 years of age with severe anaphylaxis to egg which has previously required intensive care should be referred, as per the Green Book guidelines, to a specialist for assessment with regard to receiving immunisation in hospital.</li> <li>• In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged</li> <li>• Document the reason for exclusion and any action taken in the individual's clinical records</li> <li>• Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required</li> <li>• Inform or refer to the GP or a prescriber as appropriate</li> </ul>



<b>Action to be taken if patient declines treatment</b>	<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> <li>• Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunized</li> <li>• Document advice given and the decision reached</li> <li>• Inform or refer to the GP or a prescriber as appropriate</li> </ul>
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## 8. Details of the medicine

<b>Name, form and strength of medicine</b> <i>(continued)</i>	<p>Inactivated influenza vaccine suspension in a pre-filled syringe, including:</p> <ul style="list-style-type: none"> <li>• adjuvanted quadrivalent influenza vaccine (aQIV),</li> <li>• cell-based quadrivalent influenza vaccine (QIVc),</li> <li>• egg-grown quadrivalent influenza vaccine (QIVe)</li> <li>• recombinant quadrivalent influenza vaccine (QIVr), Supemtek ▼</li> </ul> <p>Note: This PGD does not include high-dose quadrivalent influenza vaccine (QIV-HD) or trivalent influenza vaccines as these vaccines are not eligible for re-imburement under the NHS influenza vaccination programme in 2022/23</p> <ul style="list-style-type: none"> <li>• The vaccines that are available for the 2022 to 2023 influenza immunisation programme are listed here:  <a href="http://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content">www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content</a></li> <li>• <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1068455/UKHSA-2022-ovalalbumin-table-2022-2023.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1068455/UKHSA-2022-ovalalbumin-table-2022-2023.pdf</a></li> </ul> <p>Some influenza vaccines are restricted for use in particular age groups. The SPC for individual products should always be referred to</p>
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<b>Name, form and strength of medicine</b> <i>(continued)</i>	<b>Summary table of which influenza vaccines to offer (by age)</b>	
	<b>Age</b>	<b>Inactivated influenza vaccine to offer eligible individuals (see <u>Criteria for inclusion</u>)</b>
	6 months to under 2 years	Offer a suitable QIVe. For egg-allergic children under 2 years it is advised that QIVc may be offered off-label (see <u>Cautions</u> )
	2 years to 18 years	If LAIV is contraindicated (or it is otherwise unsuitable) offer QIVc <sup>3</sup>
	18 years to under 65 years	Offer QIVc or QIVr. Or, if QIVc or QIVr are not available, offer QIVe.
65 years and over <sup>4</sup>	Offer aQIV. Or, if aQIV is not available, offer QIVc or QIVr. It is recommended that aQIV is offered 'off-label' to those who become 65 years of age before 31 March 2022 (see <u>Off-label use</u> section).	
<b>Legal category</b>	Prescription Only Medicine (POM)	
<b>Black triangle ▼</b>	<ul style="list-style-type: none"> <li>• QIVc, QIVr and aQIV products are black triangle</li> <li>• QIVe vaccine from Viatrix (formerly Mylan) is black triangle</li> <li>• This information was accurate at the time of writing. See product SPCs at <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> for indication of current black triangle status</li> </ul>	
<b>Indicate any off-label use</b> (if relevant) <i>(continued)</i>	<p>The aQIV is licensed for administration to individuals aged 65 years and over. It may be administered under this PGD to 64 year olds turning 65 years of age by 31 March 2023 in accordance with the recommendations for the national influenza immunisation programme for 2022/23.</p> <p>QIVc is licensed for those aged from 2 years. QIVc, which is egg-free, can be administered under this PGD to egg allergic children aged 6 months to less than 2 years as advised by JCVI (see Appendix D of the <u>annual flu letter</u> dated 22 April 2022)</p> <p>Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <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, as part of the consent process, consider 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>	

<sup>3</sup> QIVe is suitable to offer to these children but as a second option. QIVe has not been procured by PHE for this age group.

<sup>4</sup> JCVI recommended use of QIV-HD in this age group but this is not currently available in the UK market.

<p><b>Indicate any off-label use</b> (if relevant) (continued)</p>	<ul style="list-style-type: none"> <li>Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this PGD, unless permitted off-label administration is detailed above. Refer to products' SPCs at <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and the table of <a href="#">Influenza Vaccines for the 2022 to 2023</a> season for more information.</li> </ul>
<p><b>Route/method of administration</b></p>	<p>Administer by intramuscular injection, preferably into deltoid region of the upper arm. The anterolateral aspect of the thigh is the preferred site for infants under 1 year old.</p> <p>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 (equal to 23 gauge or finer calibre such as 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.</p> <p>Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor 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/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/parent/carer should be informed about the risk of haematoma from the injection.</p> <ul style="list-style-type: none"> <li>Influenza vaccines licensed for both intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. Note: QIVc, QIVr (Supemtek ▼) and aQIV are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD.</li> <li>The vaccines should be given at separate sites, preferably in different limbs. If given in 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. If aQIV needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs.</li> </ul>

<b>Dose and frequency</b>	<ul style="list-style-type: none"> <li>• Single 0.5ml dose to be administered for the current annual flu season</li> <li>• Children in a clinical risk group aged 6 months to less than 9 years old who have not previously received any doses of influenza vaccine should be offered a second dose of vaccine at least 4 weeks later. The influenza vaccines are interchangeable, although the individual's age, recommended vaccine and vaccine licence should be considered (see <a href="#">Off-label use</a> section)</li> <li>• JCVI has advised that when a choice of either a 0.25ml or 0.5ml dose is indicated in the SPC, the 0.5ml dose of inactivated influenza vaccine should be given to individuals from age 6 months because there is evidence that this dose is effective in young children</li> </ul>
<b>Quantity to be administered</b>	Single 0.5ml dose for the current annual flu season (1 September 2022 to 31 March 2023)
<b>Maximum or minimum treatment period</b>	<ul style="list-style-type: none"> <li>• Children in a clinical risk group aged 6 months to less than 9 years old who have not previously received any doses of influenza vaccine should be offered a second dose of vaccine at least 4 weeks later. The influenza vaccines are interchangeable, although the individual's age, recommended vaccine and vaccine licence should be considered (see <a href="#">Off-label use</a> section)</li> <li>• JCVI has advised that when a choice of either a 0.25ml or 0.5ml dose is indicated in the SPC, the 0.5ml dose of inactivated influenza vaccine should be given to individuals from age 6 months because there is evidence that this dose is effective in young children</li> </ul>
<b>Storage</b>	<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>• 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 <a href="#">PHE Vaccine Incident Guidance</a></li> </ul>
<b>Adverse effects</b> (continued)	<ul style="list-style-type: none"> <li>• Pain, swelling or redness at the injection site, low-grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms after intramuscular vaccination. A small painless nodule (induration) may also form at the injection site. These symptoms usually disappear within 1 to 2 days without treatment</li> <li>• Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur</li> <li>• A higher incidence of mild post-immunisation reactions has been reported with adjuvanted compared to non-adjuvanted influenza vaccines</li> <li>• The frequency of injection site pain and systemic reactions may be higher in individuals vaccinated concomitantly with inactivated influenza vaccine and pneumococcal polysaccharide</li> </ul>

<p><b>Adverse effects</b> (continued)</p>	<p>vaccine (PPV23) compared to vaccination with influenza vaccine alone and similar to that observed with PPV23 vaccination alone. Influenza vaccine and PPV23 may be administered at the same visit</p> <ul style="list-style-type: none"> <li>• A detailed list of adverse reactions is available in the SPC for each vaccine, which are available from the electronic medicines compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></li> </ul> <p><b>Reporting procedure of adverse reactions</b></p> <ul style="list-style-type: none"> <li>• 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</li> <li>• QIVe vaccine from Viatrix (formerly Mylan), QIVc, QIVr and aQIV are black triangle. Therefore, any suspected adverse reactions should be reported via the Yellow Card Scheme</li> <li>• Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed</li> </ul>
<p><b>Records to be kept</b></p>	<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

<p><b>Verbal/Written information to be given to patient or carer</b></p>	<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> <li>• Individuals should be advised regarding adverse reactions to vaccination and reassured that the inactivated vaccine cannot cause influenza. However, the vaccine will not provide protection for about 14 days and does not protect against other respiratory viruses that often circulate during the flu season</li> <li>• Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Therefore, consideration should be given to the influenza vaccination of their household contacts</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 an adverse reaction</li> <li>• When applicable, advise the individual/parent/carer when to return for vaccination or when a subsequent vaccine dose is due</li> </ul>
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**Follow-up advice to be given to patient or carer**

- If symptoms do not improve or worsen or you become unwell, seek medical advice immediately
- When administration is postponed advise the individual/carer/parent when to return for vaccination

## 10. Appendix A

### References

1. British National Formulary (BNF) available online: <https://bnf.nice.org.uk>
2. Nursing and Midwifery “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>

### Inactivated influenza vaccination

- Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 29 October 2020.  
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>
- 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 19 July 2021. <https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan>
- Enhanced Service Specification, Seasonal influenza and vaccination programme 2021/22. <https://www.england.nhs.uk/gp/investment/gp-contract/>
- Influenza vaccines: 2021 to 2022 flu season.  
<https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content>
- Live attenuated influenza vaccine (LAIV) PGD  
<https://www.gov.uk/government/publications/influenza-vaccine-fluenz-tetra-patient-group-direction-pgd-template>
- Written instruction for the administration of seasonal ‘flu vaccination. NHS Specialist Pharmacy Service. 16 July 2020  
<https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/>
- Summary of Product Characteristics  
[www.medicines.org.uk](http://www.medicines.org.uk)
- Flu immunisation training recommendations. Updated 5 August 2020.  
<https://www.gov.uk/government/publications/flu-immunisation-training-recommendations>
- Flu Vaccinations: Supporting people with learning disabilities. Updated 25 September 2018.  
<https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities>

### General

- 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. Updated 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

- Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor
- 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



## 12. Appendix C

<p><b>Special considerations/ additional information</b> <i>(continued)</i></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>• Where locum GPs wish to be vaccinated, they should be vaccinated by their own GP (all other GP's and primary care staff are the responsibility of their employer as part of occupational health arrangements).</li> <li>• As in previous years LAIV will be the vaccine offered to the routine age cohorts for the childhood flu vaccination programme as this is the most effective vaccine for this programme. If the parent 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), a policy decision has been made that they can request an alternative injectable vaccine. PHE has procured QIVc for these children.</li> <li>• For children under the age of 16 years, those assessed as Gillick competent can self-consent (for further information on consent see <a href="#">Chapter 2</a> of 'The Green Book').</li> <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> </ul> <p>The licensed ages for the 2022/23 season influenza vaccines are:</p> <ul style="list-style-type: none"> <li>○ QIVe are licensed from 6 months of age</li> <li>○ QIVc, is licensed from 2 years of age</li> <li>○ QIVr, Supemtek ▼, is licensed from 18 years of age</li> <li>○ aQIV, is licensed for individuals aged 65 years and over (see <a href="#">Off-label</a> section)</li> </ul>
<p><b>Disposal</b></p>	<p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the <a href="#">technical memorandum 07-01: Safe management of healthcare waste</a> (Department of Health, 2013)</p>
<p><b>Drug interactions</b></p>	<ul style="list-style-type: none"> <li>• Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group</li> <li>• Inactivated influenza vaccine may be given at the same time as other vaccines (See <a href="#">Route /method of administration</a>)</li> <li>• A detailed list of drug interactions is available in the SPC for each vaccine, which are 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>• Centrally procured vaccine is available via ImmForm for children</li> <li>• Supplies for administration to adults should be ordered from the influenza vaccine manufacturers/wholesalers as in previous years</li> <li>• Should centrally procured vaccines for patients aged 18 years and over be made available, they should be ordered and used in accordance with any related guidance</li> <li>• Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3)</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>• administered 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> </ul>