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	PHE IM Influenza PGD amended to: • 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 • include vaccines for the 2019/20 season, including cell-based quadrivalent influenza vaccine (QIVc) • update cautions for egg allergy and include use of QIVc which is egg-free • include reference to the Directed Enhanced Service and offer to morbidly obese adults from 16 years of age • include reference to the Flu Vaccinations: Supporting people with learning disabilities guidance from PHE	08/05/2019
V08.00	PHE IM Influenza PGD amended to: • extend the characteristics of staff to include all registered practitioners legally able to work under PGD • 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 • update the table of recommended inactivated influenza vaccines for the 2020/21 season • update supplies section • remove reference to Fluad® brand which will not be supplied to UK this season and remove black triangle from Fluarix® Tetra • 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 • update additional information section • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	24/08/2020
V09.00	PHE Inactivated Influenza PGD amended to: • include eligible cohorts for the 2021/22 season • include the inactivated influenza vaccines for the 2021/22 season • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	23/07/2021
V10.00	Inactivated Influenza PGD amended to: • include the inactivated influenza vaccines for the 2022/23 season • include minor rewording, layout and formatting changes • Addition of the prison into the inclusion criteria	14/07/2022

V11.00	Inactivated Influenza PGD amended to: • mention consent or 'best-interests' decision in accordance with the Manx Care policy for Capacity, Best Interests Decision and Deprivation of Liberty • Include recommendations as per JCVI regarding priority of flu vaccine to be offered to vulnerable patients and patients over 65 years	14/10/2022
V11.00a	Correction to inclusion criteria to read: • individuals aged from 6 months to less than 65 years of age in a clinical risk group category listed in Chapter 19 of the Green Book	12/08/2022
V12.00	Inactivated influenza PGD amended to: • include eligible cohorts for the 2023 to 2024 season • include the recommended influenza vaccines for the 2023 to 2024 season • include updated advice on co-administration of aQIV with Shingrix® (shingles) vaccine • include minor rewording, layout and formatting changes for clarity and consistency with Manx Care PGDs, including acknowledgment of the change of PHE to UKHSA	17/07/2023
V13a	Correction to inclusion criteria to read: • people living in long-stay residential care homes or other long-stay care facilities including the prison, where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality	08/11/2023

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
Interim Executive 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
Qualifications and professional registration *(continued)*	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:# • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to the national community pharmacy seasonal influenza vaccination advanced service nor privately provided community pharmacy services) • 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 Practitioners must also fulfil all the Additional requirements. **Additionally practitioners:** • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply and administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • 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 • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation. For further information see Flu immunisation training recommendations • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines and management of the cold chain • must be competent in the recognition and management of anaphylaxis

Qualifications and professional registration *(continued)*	• must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Training in the use of PGD's
Competency assessment	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
Ongoing training and competency	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. Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHSE and other sources of medicines information. **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.

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	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 Chapter 19 of the Immunisation Against Infectious Disease: the Green Book, annual flu letter(s) and subsequent correspondence and publications from UKHSA and NHSE. **Note: This PGD does not cover the provision of occupational health schemes or peer-to-peer influenza immunisation (see NHS Specialist Pharmacy Service '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'). This PGD covers NHS commissioned services only (see Criteria for inclusion below for specified frontline staff without employer-led occupational health schemes).**

Inclusion criteria *(continued)*	For the 2023 to 2024 influenza season, influenza vaccine should be offered under the NHS influenza immunisation programme to the following groups:
	• individuals aged 65 years or over (including those becoming age 65 years by 31 March 2024)
	• individuals aged from 6 months to less than 65 years of age in a clinical risk group category listed in Chapter 19 of the Green Book such as those with:
	  ○ 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 chronic bronchitis
	  ○ chronic heart disease and vascular disease
	  ○ chronic kidney disease at stage 3, 4 or 5
	  ○ chronic liver disease
	  ○ chronic neurological disease, such as Parkinson's disease or motor neurone disease
	  ○ learning disability
	  ○ diabetes and adrenal insufficiency
	  ○ asplenia or dysfunction of the spleen
	  ○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as for cancer)
	  ○ morbidly obese adults (aged from 16 years) with a BMI of 40kg/m^2 and above
	• all pregnant women (including those women who become pregnant during the influenza season)
	• household contacts of immunocompromised individuals, specifically individuals who expect to share living

Inclusion criteria *(continued)*	accommodation on most days over the winter and, therefore, for whom continuing close contact is unavoidable • people living in long-stay residential care homes or other long-stay care facilities including the prison, where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. It does not include young offender institutions, university halls of residence or boarding schools • carers: those 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 • frontline staff without employer-led occupational health schemes, employed: ○ by a registered residential care or nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable individuals who are at increased risk from exposure to influenza ○ by a voluntary managed hospice provider, who are directly involved in the care of vulnerable individuals who are at increased risk from exposure to influenza ○ through Direct Payments (personal budgets) or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to individuals ○ to deliver social care services and are in direct contact with those who are clinically vulnerable to flu, who receive care and support services from the social care provider • children eligible for the Routine Childhood Seasonal Influenza Vaccination Programme and 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 For the 2023/24 influenza season, eligible children include: (i) children aged 2 or 3 years of age, on or before 31 August 2023[1] (ii) all primary school-aged children (from Reception to Year 6)[2,3] (iii) all secondary school-aged children (from Year 7 to 11)[4,5] Children in clinical risk groups (as above) are eligible from the age of 6 months. See also the LAIV PGD.
Exclusion criteria [4]	Individuals who:

[1] Children born between 1 September 2019 and 31 August 2021 are considered eligible.

[2] School children outside the usual age range for their class (for example those accelerated or held back a year) may be offered and given the vaccine alongside their peers.

[3] Includes children who are home-schooled or otherwise not in mainstream education.

[4] 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.

	• are less than 6 months of age • valid consent, or 'best-interests' decision in accordance with the Manx Care policy for Capacity, Best Interest and Deprivation of Liberty, has not been obtained, has not been obtained (for further information on consent, see Chapter 2 of the Green Book). • are aged 2 years to under 18 years for whom live attenuated influenza vaccine (LAIV) is suitable or not contraindicated (for instance due to the route or non-acceptance of porcine gelatine content). Note: LAIV should be given to those aged 2 to under 18 years of age in preference to inactivated influenza vaccine where possible, see LAIV PGD • have had a confirmed anaphylactic reaction to a previous dose of the vaccine • have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process (other than ovalbumin – see Cautions) • 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 (or other eligible) group listed in Chapter 19 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 • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions (including any relevant action to be taken) *(continued)* **Cautions (including any relevant action to be taken)** *(continued)*	• Facilities for management of anaphylaxis should be available at all vaccination premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). • Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route and method of administration). • 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 https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk • 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
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	• The risk to the individual of not being immunised must be taken into account. The indications for flu vaccination are not exhaustive, and the healthcare practitioner should consider the risk of flu exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from flu itself. Where appropriate, such individuals should be referred, or a PSD obtained for immunisation • In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged • Document the reason for exclusion and any action taken in the individual's clinical records • Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required • Inform or refer to the GP or a prescriber as appropriate
Action to be taken if patient declines treatment	• 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 • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Where a person lacks the capacity, in accordance with the Manx Care policy for Capacity, Best Interest and Deprivation of Liberty, a decision to vaccinate may be made in the individual's best interests. • Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunized • Document advice given and the decision reached • Inform or refer to the GP or a prescriber as appropriate

8. Details of the medicine

<table>
<tr>
<td>Name, form and strength of medicine</td>
<td>
Inactivated influenza vaccine suspension in a pre-filled syringe, including:

• adjuvanted quadrivalent influenza vaccine (aQIV) ▼
• cell-based quadrivalent influenza vaccine (QIVc)▼
• egg-grown quadrivalent influenza vaccine (QIVe)
• recombinant quadrivalent influenza vaccine (QIVr), Supemtek®▼

Note: This PGD does not include high-dose quadrivalent influenza vaccine (QIV-HD) or trivalent influenza vaccines as these vaccines are not eligible for reimbursement under the NHS influenza vaccination programme for the 2023 to 2024 season (see Recommended vaccines).

Some influenza vaccines are restricted for use in particular age groups. Refer to the vaccine's SPC and the Off-label use section for further information.

Summary table of which influenza vaccines to offer (by age)
<table>
<tr><th>Age</th><th>Inactivated influenza vaccine to offer eligible individuals (see Criteria for inclusion)</th></tr>
<tr><td>6 months to under 2 years</td><td>Offer QIVc.
If QIVc is not available, offer QIVe.
Note: The use of QIVc is off-label in this age group.</td></tr>
<tr><td>2 years to under 18 years</td><td>If LAIV is contraindicated (or it is otherwise unsuitable) offer QIVc[5].
If QIVc is not available, offer QIVe.</td></tr>
<tr><td>18 years to under 65 years</td><td>Offer QIVc or QIVr.
If QIVc or QIVr are not available[6], offer QIVe.</td></tr>
<tr><td>65 years[7] and over[8]</td><td>Offer aQIV or QIVr.
If aQIV or QIVr are not available[9], offer QIVc.
For those aged 64 who turn 65 years of age by 31 March 2024, aQIV may be offered off-label.
Note: QIVe is not recommended for those aged 65 years and over.</td></tr>
</table>
</td>
</tr>
</table>

[5] QIVc is suitable to offer to these children as a second option. QIVe has not been procured by the UKHSA for this age group and is therefore not supplied by ImmForm.
[6] QIVe should be offered only when every attempt to use QIVc or QIVr has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.
[7] Including those turning age 65 years by 31 March 2024.
[8] JCVI recommended use of QIV-HD in this age group but this is not currently available on the UK market.
[9] QIVc should be offered only when every attempt to use aQIV or QIVr has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

Legal category	Prescription Only Medicine (POM)
Black triangle▼	• QIVc, QIVr and aQIV products are black triangle. • This information was accurate at the time of writing. See product SPCs for indication of current black triangle status.
Indicate any <u>off-label use</u> (if relevant)	• Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual, parent or carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. • aQIV is licensed for administration to individuals aged 65 years and over. It may be administered under this PGD to those aged 64 years and turning 65 years of age by 31 March 2024 in accordance with the recommendations for the national influenza immunisation programme for the 2023 to 2024 season (see <u>annual flu letter</u>). • QIVc is licensed for those aged from 2 years. QIVc is also recommended by <u>JCVI</u> for children aged 6 months to less than 2 years and may be administered under this PGD. • Vaccines should be stored according to the conditions detailed in the <u>Storage</u> section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to <u>Vaccine Incident Guidance</u>. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD. **Note**: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this PGD, except where permitted off-label administration has been detailed above. Refer to product <u>SPCs</u>, and <u>Flu vaccines for the 2023 to 2024 season</u> for more information.
Route/method of administration *(continued)*	• 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. • 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. • Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the

Route/method of administration *(continued)*	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. • Influenza vaccines licensed for both intramuscular and subcutaneous administration may alternatively be administered by the subcutaneous route. Note: QIVc, QIVr and aQIV are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD. • When co-administering with other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. • The vaccines should be given at separate sites, preferably 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. • The SPCs provide further guidance on administration and are available from the electronic medicines compendium website.
Dose and frequency	• Single 0.5ml dose to be administered for the current annual flu season (1 September 2023 to 31 March 2024). • Children in a clinical risk group aged 6 months to less than 9 years old (including household contacts of immunocompromised individuals) 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 Off-label use section).
Quantity to be administered	Single dose of 0.5ml per administration dose
Maximum or minimum treatment period	• Single 0.5ml dose for the current annual flu season (1 September 2023 to 31 March 2024). Children aged 6 months to less than 9 years old in a clinical risk group (or who are a household contact of an immunocompromised individual) who have not received influenza vaccine previously should be offered a second dose of the vaccine at least 4 weeks later.

Storage	• Store at +2°C to +8°C • Do not freeze • Store in original packaging to protect from light. • 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 PHE Vaccine Incident Guidance
Adverse effects	• 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 • Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur • A higher incidence of mild post-immunisation reactions has been reported with adjuvanted compared to non-adjuvanted influenza vaccines • The frequency of injection site pain and systemic reactions may be higher in individuals vaccinated concomitantly with inactivated influenza vaccine and pneumococcal polysaccharide 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 • A detailed list of adverse reactions is available in the SPC for each vaccine, which are available from the electronic medicines compendium website. **Reporting procedure of adverse reactions** • 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: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store • QIVc, QIVr and aQIV are black triangle vaccines. All suspected adverse reactions to these vaccines should be reported via the Yellow Card reporting scheme, as these particular vaccines are newer to market. • Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed as appropriate

Records to be kept	The administration of any medication given under a PGD must be recorded within the patients' medical records Please see Appendix C for more details.

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine
Follow-up advice to be given to patient or carer	• 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 • Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Therefore, consideration should be given to the vaccination of household contacts of immunocompromised individuals • Inform the individual/carer of possible side effects and their management • The individual or carer should be advised when and where to seek appropriate advice in the event of an adverse reaction and encouraged to report this via the Yellow Card reporting scheme. • In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed • Advise the individual/carer when a subsequent vaccine dose is due, such as a single immunisation for each annual influenza season • If the individual is eligible for another vaccine on the NHS and has not received it, such as the COVID-19 vaccine, PPV23 or shingles vaccine, they should be signposted to their GP or an appropriate NHS provider.

10. Appendix A

References

- British National Formulary (BNF) available online: https://bnf.nice.org.uk
- Nursing and Midwifery "The code" available online: https://www.nmc.org.uk
- Current Health Care Professions Council standards of practice
- General Pharmaceutical Council standards
- Electronic medicines compendium available online: https://www.medicines.org.uk

Inactivated influenza vaccination

- Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 16 September 2022. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Collection: Annual Flu Programme. https://www.gov.uk/government/collections/annual-flu-programme
- The national flu immunisation programme plan 2023 to 2024: supporting letter https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan
- Flu vaccines for the 2023 to 2024 season, updated 25 May 2023 https://www.gov.uk/government/publications/flu-vaccines-for-the-current-season/flu-vaccines-for-the-2023-to-2024-season
- 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 https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/
- Summary of Product Characteristics www.medicines.org.uk
- Flu immunisation training recommendations. Updated 12 August 2022. 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

- NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/
- 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
- UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation
- 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

Special considerations/ additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination. 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. For children under the age of 16 years, those assessed as Gillick competent can self-consent (for further information on consent, see Chapter 2 of the Green Book). Individuals with learning disabilities may require reasonable adjustments to support vaccination (see Flu vaccinations: supporting people with learning disabilities). A PSD may be required. The licensed ages for the 2023 to 2024 season influenza vaccines are: • QIVe licensed from 6 months of age • QIVc licensed from 2 years of age (see Off-label use section) • QIVr licensed from 18 years of age • aQIV licensed from 65 years of age (see Off-label use section)

Disposal	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 arrangements and NHSE guidance in (HTM 07-01): Management and disposal of healthcare waste
Drug interactions	• Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group • Influenza vaccines can be co-administered with other vaccines including COVID-19 and shingles vaccines (see Route and method of administration). Initially, a seven day interval was recommended between Shingrix® (shingles) vaccine and adjuvanted influenza vaccine (aQIV) because the potential reactogenicity from two adjuvanted vaccines may reduce the tolerability in those being vaccinated. Interim data from a US study on co-administration of Shingrix® with adjuvanted seasonal influenza vaccine is reassuring. Therefore, an appointment for administration of the seasonal influenza vaccine can be an opportunity to also provide shingles vaccine (see Shingrix® PGD). • Where aQIV is given with other vaccines, including other adjuvanted vaccines, the adverse effects of both vaccines may be additive and should be considered when informing the recipient. Individuals should also be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval. • A detailed list of drug interactions is available in the SPC for each vaccine, which are available from the electronic medicines compendium website.
Supplies	• Centrally procured vaccine is available via ImmForm for children • Supplies for administration to adults should be ordered from the influenza vaccine manufacturers/wholesalers as in previous years • Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).
Records *(Continued)*	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken

Records *(Continued)*	• administered via PGD • Records should be signed and dated (or a password-controlled immuniser's record on e-records) • All records should be clear, legible and contemporaneous. • 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 • 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 • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy