UK Health Security Agency

NHS England

Publications gateway number: GOV-15001

Inactivated influenza vaccine Patient Group Direction (PGD)

This PGD is for the administration of inactivated influenza vaccine to individuals in accordance with the national influenza immunisation programme.

This PGD is for the administration of inactivated influenza vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.[1]

Reference no:	Inactivated influenza PGD
Version no:	v12.00
Valid from:	1 September 2023
Expiry date:	1 April 2024

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[2]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter Section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA PGD templates for authorisation can be found from Immunisation patient group direction (PGD) templates

Any concerns regarding the content of this PGD should be addressed to: immunisation@ukhsa.gov.uk

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Contacts listed on pages 4 & 5 of this PGD

[1] This PGD is not relevant to the national community pharmacy seasonal influenza vaccination advanced service which has its own PGD (see Pharmacy Influenza Vaccination PGD)

[2] This includes any relevant amendments to legislation

Change history

Version number	Change details	Date
V01.00 to V08.00	See earlier version of this PGD for change details.	18 August 2015 to 24 August 2020
V09.00	PHE Inactivated Influenza PGD amended to: • include eligible cohorts for the 2021 to 2022 season • include the inactivated influenza vaccines for the 2021 to 2022 season • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	23 July 2021
V10.00	Inactivated Influenza PGD amended to: • include primary care contractors (primary medical services, pharmaceutical services, primary dental services or general ophthalmic services) and their frontline staff, including locums • mention consent or 'best-interests' decision in accordance with the Mental Capacity Act 2005 • update additional information and drug interactions sections • update for change of organisation from PHE to UKHSA • web addresses hyperlinked into body text for clarity and consistency with other UKHSA PGDs	12 October 2021
V11.00	Inactivated influenza PGD amended to: • include only eligible cohorts for the 2022 to 2023 season • include the inactivated influenza vaccines for the 2022 to 2023 season • remove the exclusion of 'individuals who are less than 2 years of age and have had a severe anaphylactic reaction to egg which has previously required intensive care' and update cautions and off-label section to advise egg-free cell-based influenza vaccine is offered off-label to these individuals in accordance with JCVI advice and the annual flu letter • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs	8 August 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 August 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	17 July 2023

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead author)	Christina Wilson Lead Pharmacist – Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		17 July 2023
Doctor	Jamie Lopez-Bernal Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		17 July 2023
Registered Nurse	David Green, Nurse Consultant for Immunisation Immunisation and Vaccine Preventable Diseases Division, UKHSA		17 July 2023

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been approved by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSE
Rosie Furner	Pharmacist, Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Urgent/Unscheduled Care Lead, Frailty/ Proactive Care Lead, Southbourne Surgery
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London
Conall Watson	Consultant Epidemiologist - Influenza and seasonal respiratory viruses, Immunisation and Vaccine Preventable Diseases Division, UKHSA

2. Organisational authorisations

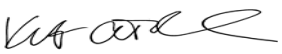
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHSE North East and Yorkshire authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
NHS England (NHSE) commissioned immunisation services or NHS Trust providing immunisation services.
Limitations to authorisation
Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations/providers commissioned by NHSE North East and Yorkshire (NEY) to deliver immunisation programmes within the whole of the NHSE region of North East and Yorkshire

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Assistant Medical Director and Responsible Officer, **NHS England –NEY**	**Dr James Gossow**		**14th August 2023**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
NHSE NEY PGD Governance assurance review (Medicines Optimisation Pharmacist Lead, NHS NECS	**Kurt Ramsden**		**11th August 2023**
Screening and Immunisation Place Lead, Specialist Community Public Health Nurse – Health Visitor.	**Emma Nebard**		**4th August 2023**

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation teams. See area-specific contacts below:

For North East and North Cumbria Area (i.e. Northumberland, Tyne & Wear, Durham Darlington and Tees and North Cumbria) use the following:

NHS England Screening and Immunisation Team: email england.cane.screeningimms@nhs.net or NECS Medicine Optimisation Pharmacists: Kurt Ramsden: kurtramsden@nhs.net or Sue White: sue.white14@nhs.net

Please note - All North East and North Cumbria PGDs can be found at:

https://medicines.necsu.nhs.uk/resources/patient-group-directions/

For Yorkshire and Humber Area use the following:

West Yorkshire - england.wysit@nhs.net

South Yorkshire and Bassetlaw - england.sybsit@nhs.net

North Yorkshire and Humber ENGLAND.NYAHSIT@nhs.net

Health Protection Team Acute Response Centre (ARC): Contact Number: 0113 3860 300.

Please note - All Yorkshire and Humber PGDs can be found at: https://www.england.nhs.uk/north-east-yorkshire/our-work/information-for-professionals/pgds /

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Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): • 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. Check Section 2 Limitations to authorisation to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.
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 • 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.**
Continued training requirements	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.

4. Clinical condition or situation to which this PGD applies

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).**

Criteria for inclusion
 	
(continued over page)
	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 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 where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, 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

Criteria for inclusion (continued)	○ 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[3] (ii) all primary school-aged children (from Reception to Year 6)[4,5] (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.
Criteria for exclusion[6]	Individuals for whom valid consent, or 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent, see Chapter 2 of the Green Book). Individuals who: • are less than 6 months of age • 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[7] (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 over page)	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 a suitable egg-free vaccine, for instance QIVc or QIVr.

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

[4] 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.

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

[6] 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.

[7] 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's SPC for details.

Cautions including any relevant action to be taken (continued)	Individuals with a less severe egg allergy can be immunised in any setting using a suitable egg-free vaccine, or an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to 0.06 micrograms per 0.5 ml dose). For details of the influenza vaccines available for the current season and their ovalbumin content, follow this link. 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.
Action to be taken if the patient is 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 the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration (see Additional Information). Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached. Inform or refer to the individual's GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy.

5. Description of treatment

<table>
<tr><td>Name, strength and formulation of drug</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</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[8].
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[9], offer QIVe.</td></tr>
<tr><td>65 years[10] and over[11]</td><td>Offer aQIV or QIVr.
If aQIV or QIVr are not available[12], 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>
<tr><td>Legal category</td><td>Prescription only medicine (POM).</td></tr>
<tr><td>Black triangle▼</td><td>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.</td></tr>
</table>

[8] 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.

[9] 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.

[10] Including those turning age 65 years by 31 March 2024.

[11] JCVI recommended use of QIV-HD in this age group but this is not currently available on the UK market.

[12] 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.

Off-label use	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 annual flu letter). QIVc is licensed for those aged from 2 years. QIVc is also recommended by JCVI 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 Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to Vaccine Incident Guidance. 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 SPCs, and Flu vaccines for the 2023 to 2024 season for more information.
Route and method of administration	Administer by intramuscular injection, preferably into the deltoid muscle 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 (23 gauge or 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 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 or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. A fine needle (23 gauge or 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 or 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.

(continued over page)

Route and method of administration (continued)	Shake vaccine suspensions gently before administration (QIVr, Supemtek® solution for injection does not require shaking before administration). Inspect the vaccine visually prior to administration for any foreign particulate matter or discolouration to ensure appearance is consistent with the description in the vaccine's SPC. The SPCs provide further guidance on administration and are available from the electronic medicines compendium website.
Dose and frequency of administration	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).
Duration of treatment	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.
Quantity to be supplied and administered	Single dose of 0.5ml per administration.
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).
Storage	Store at +2°C to +8°C. Do not freeze. Store in original packaging in order 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 Vaccine Incident Guidance.
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 (continued over page)	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

Drug interactions (continued)	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.
Identification and management of adverse reactions	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 or at any interval from each other. 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 and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching 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.
Written information to be given to patient or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. For information leaflets in accessible formats and alternative languages, please visit Home–Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic Medicines Compendium.
Patient advice and follow-up treatment	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.

(continued over page) **Patient advice and follow-up treatment** (continued)	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. Inform the individual, parent or carer of possible side effects and their management. The individual, parent or carer should be advised when to seek medical advice in the event of an adverse reaction and encouraged to report this via the Yellow Card reporting scheme. When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations and 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)
Records	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 immunisation declined • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or password controlled on e-records). All records should be clear, legible and contemporaneous. As a wide variety of influenza vaccines are available on the UK market each year, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records. It is important that vaccinations given either at a general practice or elsewhere (for example at antenatal clinics) are recorded on appropriate health records for the individual (using the appropriate clinical code) in a timely manner. If given elsewhere, systems should be in place to ensure a record of vaccination is returned to the individual's general practice to allow clinical follow-up and to avoid duplicate vaccination.

(continued over page) **Records** (continued)	For pregnant women, also record immunisation in the hand-held and electronic maternity record (if available). A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**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
(continued over page)	

Key references (continued)	• 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

7. Practitioner authorisation sheet

Inactivated Influenza PGD v12.00 Valid from: 1 September 2023 Expiry: 1 April 2024

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Practitioner

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

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD