UK Health Security Agency

NHS

Publications gateway number: GOV-16449

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:	v13.00
Valid from:	1 September 2024
Expiry date:	1 April 2025

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). **Sections 2 and 7 can be amended within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisations using the PGD. The fields in sections 2 and 7 cannot be used to alter, amend or add to the clinical contents. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.**

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

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

[2] This includes any relevant amendments to legislation

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

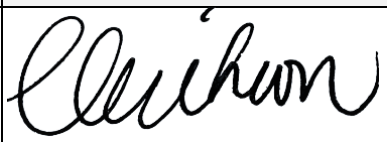
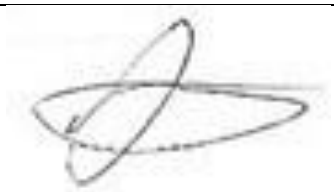
Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: your local screening and immunisation team

Change history

Version number	Change details	Date
v1.00 to v9.00	See earlier version of this PGD for change details.	18 August 2015 to 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
v13.00	Inactivated influenza PGD amended to: • update eligibility criteria for the 2024 to 2025 season • advise earlier immunisation of pregnant women and children from 1 September; remaining cohorts to commence October (precise date TBC by NHS England) • reflect reduction in QIVc licensed age from 2 years to 6 months of age • incorporate amendments to the flu letter from 12 June 2024, including choice of vaccines recommended by age; separation of the 18 to 64 year cohort into 18 to 59 years and 60 to 64 years to reflect QIV-HD licensing • include pharmacy technicians as an additional professional group, as outlined in the relevant amendments to HMR 2024 • include minor rewording, layout and formatting changes for consistency with other UKHSA PGDs	20 June 2024

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		14 June 2024
Doctor	Jamie Lopez-Bernal Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 June 2024
Registered Nurse (Chair of the Expert Panel)	David Green Nurse Consultant for Immunisation Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 June 2024

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Committee.

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
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Specialist Pharmacist, Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Primary Care Based, Southbourne Surgery
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, 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

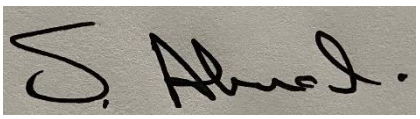
1. Organisational authorisations

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.

NHS England (South East) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England commissioned immunisation services within the NHS England South East Region.
Limitations to authorisation
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England (South East) must be used. This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director for System Improvement and Professional Standards	**Dr Shahed Ahmad**		**10 July 2024**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team

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.

2. Characteristics of staff

Qualifications and professional registration	**All practitioners should only administer vaccinations where it is within their scope of clinical practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below.** 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 and pharmacy technicians 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 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 Training for registered healthcare practitioners. 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 (continued over page)	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.

Continued training requirements (continued)	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.

3. 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 Influenza vaccine written instruction templates for adoption). 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 2024 to 2025 influenza season, influenza vaccine should be offered under the NHS influenza immunisation programme to the following groups: **From 1 September 2024:** • all pregnant women (including those women who become pregnant during the influenza season) • 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. See the LAIV PGD for more information. For the 2024/2025 influenza season, eligible children include: (i) children aged 2 or 3 years of age, on or before 31 August 2024[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] (iv) those in clinical risk groups (as outlined below) aged from 6 months to less than 18 years **The precise date from which all other eligible individuals may be vaccinated will be communicated by NHSE; at the time of writing, this has been planned from October.** **Upon announcement of this date, this PGD may be used for vaccination of the following cohorts:** • individuals aged 65 years or over (including those becoming age 65 years by 31 March 2025) • individuals aged 18 years to under 65 years in a clinical risk group category listed in Chapter 19 of the Green Book: **Clinical risk groups** ○ 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

[3] Children born between 1 September 2020 and 31 August 2022 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.

Criteria for inclusion (continued)	○ 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 • 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 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
Criteria for exclusion[6]	Individuals who have not given valid consent (or for whom a 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. Several resources are available to inform consent (see written information to be given to individual, parent or carer section). 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)

[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	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. 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 individual 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 individual 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. Further information on consent can be found in 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.

4. 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)
high-dose quadrivalent influenza vaccine (QIV-HD)▼

Some influenza vaccines are restricted for use in particular age groups. Refer to the vaccine's SPC, recommended vaccines as outlined in the flu letter and the off-label use section for further information.
Summary table of which inactivated influenza vaccines to offer (by age)
<table>
<tr><th>Age</th><th>Inactivated influenza vaccine to offer eligible individuals</th><th>Notes</th></tr>
<tr><td>6 months to under 2 years</td><td>Offer QIVc.
If QIVc is not available, offer QIVe.</td><td></td></tr>
<tr><td>2 years to under 18 years</td><td>If LAIV is contraindicated (or it is otherwise unsuitable) offer QIVc.
If QIVc is not available, offer QIVe.</td><td>QIVe not available via ImmForm for this cohort.</td></tr>
<tr><td>18 years to 59 years (including in pregnancy)</td><td>Offer QIVc.
If QIVc is not available[8], offer QIVe.</td><td></td></tr>
<tr><td>60 to 64 years</td><td>Offer QIVc or QIV-HD.
If QIVc or QIV-HD is not available[9], offer QIVe</td><td></td></tr>
<tr><td>65 years and over, including those turning 65 by 31 March 2025</td><td>Offer aQIV or QIV-HD.
If aQIV or QIV-HD are not available[10], offer QIVc.
Note: QIVe is not recommended for those aged 65 years and over.</td><td>aQIV may be offered off-label for those aged 64 who turn 65 years of age by 31 March 2025.</td></tr>
</table>
</td></tr>
<tr><td>Legal category</td><td>Prescription only medicine (POM).</td></tr>
<tr><td>Black triangle▼</td><td>QIVc, QIV-HD and aQIV products are designated as black triangle medicines. Being newer vaccines, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for these products. All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme.
This information was accurate at the time of writing. See product SPCs for indication of current black triangle status.</td></tr>
</table>

[8] QIVe should be offered only when every attempt to use QIVc has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

[9] QIVe should be offered only when every attempt to use QIVc or QIV-HD has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed

[10] QIVc should be offered only when every attempt to use aQIV or QIV-HD 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 outside of product licence but in accordance with national guidance. 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 2025, in accordance with the recommendations for the national influenza immunisation programme for the 2024 to 2025 season (see annual flu letter). 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, with the exception of off-label administration of aQIV as detailed above. Refer to product SPCs, and Flu vaccines for the 2024 to 2025 season for more information.
Route and method of administration (continued over page)	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 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. 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. 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 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. Shake vaccine suspensions gently before administration. Visually inspect the vaccine prior to administration for any foreign particulate matter, discolouration or other variation of expected appearance from that described in the vaccine's SPC. Discard the vaccine in accordance with local procedures, should any of these occur. Check product name, batch number and expiry date before administration.

Route and method of administration (continued)	The SPCs provide further guidance on administration.
Dose and frequency of administration	**QIVc, QIVe and aQIV**: Single 0.5ml dose to be administered for the current annual flu season (1 September 2024 to 31 March 2025). **QIV-HD only:** **Single 0.7ml dose** during the current annual flu season. 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	As outlined in dose and frequency of administration above.
Quantity to be supplied and administered	**QIVc, QIVe and aQIV**: Single dose of 0.5ml per administration. **QIV-HD**: Single dose of 0.7ml 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 or their 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, vaccines that have 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	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste 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): safe and sustainable management 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 7 day interval was recommended between Shingrix® (shingles) vaccine and adjuvanted influenza vaccine (aQIV) because the potential reactogenicity from 2 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

Drug interactions (continued)	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.
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 one 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.
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, QIV-HD 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 individual or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Offer promotional material as appropriate: • the flu vaccination: who should have it and why (as updated for winter 2024 to 2025) • protect yourself from flu, have the flu vaccine: information for people with a learning disability leaflet 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.
Advice and follow-up treatment (continued over page)	Individuals should be advised regarding adverse reactions to vaccination and reassured that the inactivated vaccine cannot cause influenza. However, the vaccine

Advice and follow-up treatment (continued)	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 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. In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed. 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. **Timing of doses** As outlined in the flu letter, vaccination of pregnant women should begin from 1 September, to ensure that as many newborn babies as possible are protected during the flu season. Children, including those in clinical risk groups should be vaccinated from 1 September, as early as delivery and supply of suitable vaccines allow. Vaccination of remaining cohorts should commence from October (precise date to be confirmed by NHSE). There may be a small number of other adults for whom delaying vaccination is not advised, for example individuals due to commence immunosuppressive treatment before the announced start date for vaccination. Clinicians should use clinical judgement to bring forward vaccination in such exceptions and when vaccine supply becomes available. A PSD should be used.
Records (continued over page)	The practitioner must ensure the following is recorded: • 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

Records (continued)	• 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. 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.

5. Key references

Key references	**Inactivated influenza vaccination** • Immunisation Against Infectious Disease: The Green Book, Chapter 19. Updated 3 November 2023. 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 2024 to 2025 letter, published 12 March 2024 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2024-to-2025/national-flu-immunisation-programme-2024-to-2025-letter • Statement of amendment to the annual flu letter for 2024 to 2025, published 12 June 2024 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2024-to-2025/statement-of-amendment-to-the-annual-flu-letter-for-2024-to-2025-12-june-2024 • JCVI advice on influenza vaccines for the 2024/ 2025 season, updated 25 August 2023 https://app.box.com/s/t5ockz9bb6xw6t2mrrzb144njplimfo0/file/1289995245447 • All influenza vaccines marketed in the UK for the 2024 to 2025 season, updated 21 March 2024 https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk • Influenza vaccine written instruction templates for adoption. NHS Specialist Pharmacy Service, published 4 March 2024 https://www.sps.nhs.uk/articles/influenza-vaccine-written-instruction-templates-for-adoption/ • Flu immunisation training recommendations, updated 8 August 2023 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 and sustainable 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 13 October 2023. https://www.gov.uk/government/publications/consent-the-green-book-chapter-2 • National Minimum Standards and Core Curriculum for Immunisation Training, published 7 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 27 March 2017 https://www.nice.org.uk/guidance/mpg2
(continued over page)	

Key references (continued)	• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources • 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 • UK Statutory Instruments 2024, Number 729. The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024, published 29 May 2024 https://www.legislation.gov.uk/uksi/2024/729/introduction/made

7. Practitioner authorisation sheet

Inactivated Influenza PGD v13.00 Valid from: 1 September 2024 Expiry: 1 April 2025

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