



NHS publishing approval reference: PRN00639

Community Pharmacy Inactivated influenza vaccine Patient Group Direction (PGD)

This PGD is for the administration of inactivated influenza vaccine to adults in accordance with the community pharmacy seasonal influenza vaccination advanced service and national influenza immunisation programme.

This PGD is for the administration of inactivated influenza vaccine by practitioners delivering the community pharmacy seasonal influenza vaccination advanced service.

Reference: Community Pharmacy Influenza Vaccination 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 for authorisation by NHS England (NHSE) to facilitate delivery of the national immunisation programme in England.

NHSE and community pharmacy contractors must not alter or amend the clinical content of this document (sections 3, 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. Section 2 may be amended by NHSE only. <u>Section 7</u> is to be completed by the community pharmacy contractor providing the advanced service.

Operation of this PGD is the responsibility of NHSE as the commissioner and the community pharmacy contractor as the service provider. The final authorised copy of this PGD should be kept by NHSE and community pharmacy contractors for 8 years after the PGD expires.

A practitioner must be authorised by name to work according to the current version of this PGD by signing section 7. A manager with the relevant level of authority should also provide a countersignature.

Providers must check that they are using the current version of this PGD. Amendments may become necessary prior to the published expiry date. The current version of the community pharmacy seasonal influenza vaccination advanced service PGD (Pharmacy Influenza Vaccination PGD) can be found at: NHS England » Community Pharmacy Seasonal Influenza Vaccine Service

Any enquiries regarding this PGD should be addressed to: ENGLAND.communitypharmacy@nhs.net

Change history

| Version number | Change details | Date |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| V01.00 - V07.00 | See earlier version of this PGD for change details. | 18 August 2015 – 24 August 2020 |
| V08.00 | Pharmacy Influenza Vaccination PGD amended to: include registered professionals who can legally supply and administer under a PGD 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 | 27 July 2021 |
| V09.00 | Pharmacy Influenza Vaccination 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 |
| V10.00 | Pharmacy Influenza Vaccination PGD amended to: • include only eligible cohorts for the 2022 to 2023 influenza season • include the inactivated influenza vaccines for the 2022 to 2023 season • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs | 28 June 2022 |
| V11.00 | Pharmacy Influenza Vaccination PGD amended to remove declaration of competence for vaccination services from additional requirements under staff characteristics | 5 September 2022 |
| V12.00 | Community Pharmacy Influenza Vaccination 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 Division UKHSA | Cluchum | 17 July 2023 |
| Doctor | Jamie Lopez-Bernal Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA | 2 | 17 July 2023 |
| Registered Nurse (Chair of Expert Panel) | David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA | Daisen. | 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 ratified by the UKHSA Medicines Governance Group.

In addition to the signatories above, the Working Group included:

| Name | Designation |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Marie-Claire Demblon | Head of Unit – Vaccine and Immunisation Commissioning Policy Team NHSE |
| Jane Devenish | Head of Vaccination Policy – Community Pharmacy, NHSE |
| Amanda Marshall | Senior Policy Lead – Local Vaccination Service, Primary Care, Community Services and Strategy Directorate, NHSE |
| David Onuoha | Service Development Manager, Community Pharmacy England |
| Conall Watson | Consultant Epidemiologist – Influenza and seasonal respiratory viruses, Immunisation and Vaccine Preventable Diseases Division, UKHSA |

Expert Panel

| Name | Designation | |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Nicholas Aigbogun | Consultant in Communicable Disease Control, Yorkshire and Humber HealthProtection 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 ProtectionTeam, 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 | |

2. Organisational authorisations

NHSE accepts responsibility for governance of this PGD. Any community pharmacy contractor providing the advanced service must work strictly within the terms of this PGD and The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions, covering the advanced service, published in the Drug Tariff. Any deviation will be treated as a serious contractual breach.

NHSE authorises this PGD for use by community pharmacy contractors delivering the community pharmacy seasonal influenza vaccination advanced service.

| Organisational approval (legal requirement) | | | | |
|---------------------------------------------------------------------------|-----------------|---------------|---------------|--|
| Role | Name | Sign | Date | |
| Director of Public Health Commissioning and Operations, NHS England | Deborah Tomalin | SebooliTorich | 4 August 2023 | |

Enquiries regarding the use of this PGD may be directed to: ENGLAND.communitypharmacy@nhs.net

The community pharmacy contractor must complete the practitioner authorisation sheet included at the end of this PGD (see <u>Section 7</u>).

3. Characteristics of Staff

Qualifications and Practitioners must only work under this PGD where they are competent to do professional so. Practitioners working to this PGD must also be one of the following registration registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): pharmacists currently registered with the General Pharmaceutical Council (GPhC) nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • 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. Additional Additionally, practitioners: requirements must be authorised by name as an approved practitioner under the current terms of this PGD before working to it (by completion of Section 7) must have undertaken appropriate training for working under PGDs for supply and administration of medicines as required by the community pharmacy advanced service specification: seasonal influenza vaccination must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs) must be familiar with the vaccine products and alert to changes in their Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the 'Green Book'), and the national immunisation 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 further information see Flu immunisation training recommendations must be competent to undertake immunisation and to discuss issues related to seasonal influenza 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 The practitioner must be authorised by name, under the current NHSE authorised version of this PGD before working under its authority. **Continued training** Practitioners should ensure they are up to date with relevant issues and requirements clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from UKHSA. NHSE and other sources of medicines information.

would be outside the scope of this PGD, the individual should be referred to their GP for vaccination.

Note: The most current national recommendations should be followed. However, if updated recommendations mean that to vaccinate the individual

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 adults for the prevention of influenza infection, in accordance with the community pharmacy seasonal influenza vaccination advanced service, the national immunisation programme and recommendations given in Chapter 19 of the Immunisation Against Infectious Disease: 'The Green Book', annual flu letter and subsequent correspondence and publications from UKHSA and NHSE.

Criteria for inclusion

For the 2023 to 2024 influenza season, influenza vaccine should be offered at NHS expense to the following groups under the community pharmacy seasonal influenza vaccination advanced service:

- individuals aged 65 years or over (including those becoming age 65 years by 31 March 2024)
- adults aged from 18 years to under 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
 - o chronic heart disease and vascular disease
 - o chronic kidney disease at stage 3, 4 or 5
 - o chronic liver disease
 - chronic neurological disease, such as Parkinson's disease or motor neurone disease
 - learning disability
 - o diabetes and adrenal insufficiency
 - o asplenia or dysfunction of the spleen
 - a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as for cancer)
 - o morbidly obese adults with a BMI of 40kg/m² and above

Adults aged from 18 years to under 65 years of age who are:

- 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
- 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: individuals 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 health and social care workers 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

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Criteria for inclusion o through Direct Payments (personal budgets) or Personal Health Budgets. such as Personal Assistants, to deliver domiciliary care to individuals (continued) o 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 exclusion1 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 18 years of age have had a confirmed anaphylactic reaction to a previous dose of the have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process² (other than ovalbumin – see Cautions) • have received a complete dose of the recommended influenza vaccine for the current season are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) Note: This PGD covers NHS commissioned services only. It may not be used for the provision of inactivated influenza vaccine via occupational health schemes or peer-to-peer immunisation. A written instruction should instead be used, for which the NHS Specialist Pharmacy Service produce a template. Facilities for management of anaphylaxis should be available at all vaccination Cautions including any relevant action to be premises (see Chapter 8 of the Green Book and advice issued by the taken 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. 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 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.

¹ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for administration of vaccine will be required

² 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.

| Action to be taken if the patient is excluded | The risk to the individual of not being immunised should be taken into account. The indications for flu vaccination are not exhaustive, and the practitioner should take into account 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 to their GP. | |
|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| | Individuals under 18 years of age who are in a clinical risk group or otherwise eligible for influenza vaccination for the 2023 to 2024 season, should be referred to their GP or an appropriate local NHS service provider. | |
| | In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged. | |
| | Communicate and document the reason for exclusion and any action taken in the individual's clinical records. | |
| 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. 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 or carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. | |
| | Document advice given and decision reached and inform individual's GP as appropriate. | |
| Arrangements for referral for medical advice | Refer to individual's GP. | |

5. Description of Treatment

| Name, strength and formulation of drug | 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) | | |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| | Age Inactivated influenza vaccine to offer eligible individuals | | |
| | 18 years to under 65 years | Offer QIVc or QIVr. If QIVc or QIVr are not available ³ , offer QIVe. | |
| | 65 years ⁴ and over ⁵ | Offer aQIV or QIVr. If aQIV or QIVr are not available ⁶ , 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. | |
| Legal category | Prescription only medicine (POM). | | |
| Black triangle ▼ | QIVc, QIVr and aQIV vaccines are black triangle. This information was accurate at the time of writing. See product SPCs , for indication of current black triangle status. | | |

³ 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.

⁴ Including those turning age 65 years by 31 March 2024.

⁵ JCVI recommended use of QIV-HD in this age group but this is not currently available on the UK market.

⁶ 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 or carer the vaccine is being offered in accordance with national guidance but 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 the annual flu letter).

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 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.

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 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.

Shake vaccine suspensions gently before administration. Note QIVr (Supemtek® solution for injection) does not require shaking before administration.

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| Route and method of administration (continued) Dose and frequency | Inspect the vaccine visually prior to administration for foreign particulate matter or discolouration to ensure appearance is consistent with the description in the vaccine's SPC . The SPC for each vaccine provides further guidance on administration and is available from the electronic medicines compendium website. Single 0.5ml dose to be administered for the current annual flu season (1 |
|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| of administration | September 2023 to 31 March 2024). |
| Duration of treatment | Single 0.5ml dose for the current annual flu season. |
| Quantity to be supplied and administered | Single dose of 0.5ml per administration. |
| Supplies | Providers should order influenza vaccines for adults from the influenza vaccine manufacturers or pharmaceutical wholesalers as in previous years. |
| Storage | Store between +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 discharged vaccines in a syringe, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local 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 <u>electronic medicines compendium</u> website. |

Identification and Pain, swelling or redness at the injection site, low-grade fever, malaise, management of shivering, fatigue, headache, myalgia and arthralgia are among the commonly adverse reactions 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 on the same day or at any interval from each other. A detailed list of adverse reactions associated with inactivated influenza vaccine is available in the SPC for each vaccine, which are available from the electronic medicines compendium website. Healthcare professionals, individuals and carers are encouraged to report Reporting procedure of adverse reactions 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 products 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 theindividual's record and the individual's GP should be informed as appropriate. Written information Offer the marketing authorisation holder's patient information leaflet (PIL)

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 <u>electronic Medicines Compendium</u>.

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 anddoes 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 or 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 <u>Yellow Card reporting scheme</u>. 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 or 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.

Special considerations and additional information

The practitioner should have immediate access to adrenaline (epinephrine) 1 in 1,000 injection and 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.

Individuals who are not registered with a GP practice may be vaccinated at the professional discretion of the practitioner, weighing up risks and benefits for the individual. They should be encouraged to register with a GP as appropriate to their circumstances or be referred to appropriate alternative medical services as required.

Records

Record:

- that valid informed consent was given
- name of individual, address, date of birth and GP practice with whomthe individual is registered (or record where an individual is not registered with a GP and that appropriate advice has been given)
- eligible or clinical risk group indication for immunisation
- 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 not vaccinated
- details of any adverse drug reactions and actions taken
- supplied via PGD

Records should be signed and dated or if using electronic records, the immuniser's account should be password protected such as to provide an electronic signature to the vaccination record.

All records should be clear, legible, contemporaneous and in line with the community pharmacy seasonal influenza immunisation advanced service specification.

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, batchnumber and site at which each vaccine is given is accurately recorded in the individual's records.

It is important that vaccinations administered are recorded in a timely manner. A record of the vaccination should be returned to the individual's GP practice (as specified in the service specification) 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).

Records of all individuals receiving treatment under this PGD should also be kept for audit purposes and post-payment verification.

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/publications/influenza-the-green-book-chapter-19
- Collection: Annual Flu Programme https://www.gov.uk/government/collections/annual-flu-programme
- Community Pharmacy Advanced Service Specification: Seasonal Influenza https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service/
- The national flu immunisation programme 2023 to 2024: supporting letter. https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan
- All influenza vaccines marketed in the UK for the 2023 to 2024 season https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk
- Flu vaccines for the 2023 to 2024 season, updated 25 May 2023
 https://www.gov.uk/government/publications/flu-vaccines-for-the-current-season
- Competency assessment tools for vaccination services https://www.cppe.ac.uk/services/declaration-of-competence
- Flu immunisation training recommendations. Updated 12 August 2022.
 https://www.gov.uk/government/publications/flu-immunisation-training-recommendations
- Summary of Product Characteristics www.medicines.org.uk

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-
 - 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-corecurriculum-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
- 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

Community Pharmacy Influenza Vaccination PGD v12.00. Valid from: 1 September 2023 Expiry: 1 April 2024

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 practice 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 | |
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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 practitioners 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.

A copy of this PGD with completed practitioner authorisation sheet should be retained and available at the pharmacy premises as a record of those practitioners authorised to work under this PGD.