UK Health Security Agency

**NHS publishing approval reference:** PAR1128

# 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.

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| Reference: | Pharmacy Influenza Vaccination PGD |
| Version no: | v09.00 |
| Valid from: | 21 October 2021 |
| Expiry date: | 31 March 2022 |

**UK Health Security Agency (UKHSA) has developed this PGD for authorisation by NHS England and NHS Improvement (NHSEI) to facilitate delivery of the national immunisation programme.**

NHSEI 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 NHSEI only. Section 7 is to be completed by the community pharmacy contractor providing the advanced service.

Operation of this PGD is the responsibility of NHSEI as the commissioner and the community pharmacy contractor as the service provider. The final authorised copy of this PGD should be kept by NHSEI 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 counter signature.**

Providers must check that they are using the current version of the 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

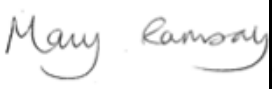
Any enquiries regarding this PGD should be addressed to: ENGLAND.communitypharmacy@nhs.net

## Change History

| Version number | Change details | Date |
|---|---|---|
| V01.00 – V05.00 | See earlier version of this PGD for change details. | 18 August 2015 – 10 August 2018 |
| V06.00 | Pharmacy Influenza Vaccination PGD amended to:<br>• include vaccines for the 2019/20 season, including cell-based quadrivalent influenza vaccine (QIVc)<br>• update cautions for egg allergy and include use of QIVc which is egg free for individuals with a severe anaphylaxis to egg which has previously required intensive care | 08 May 2019 |
| V07.00 | Pharmacy Influenza Vaccination PGD amended to:<br>• add paragraph on document retention to the front page<br>• include household contacts of those on the NHS Shielded Patient List, health and social care workers employed through Direct Payments or Personal Health Budgets, and potential in season extension of the programme to individuals from 50 years of age<br>• update the table of recommended inactivated influenza vaccines for the 2020/21 season<br>• remove reference to Fluad® brand which will not be supplied to UK this season and remove black triangle from Fluarix® Tetra<br>• remove reference to barium sulphate which is no longer listed in the adjuvanted trivalent influenza influenza vaccine SPC as a residue of the manufacturing process<br>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs | 24 August 2020 |
| V08.00 | Pharmacy Influenza Vaccination PGD amended to:<br>• include registered professionals who can legally supply and administer under a PGD<br>• include eligible cohorts for the 2021/22 season<br>• include the inactivated influenza vaccines for the 2021/22 season<br>• 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:<br>• include primary care contractors (primary medical services, pharmaceutical services, primary dental services or general ophthalmic services) and their frontline staff, including locums<br>• mention consent or 'best-interests' decision in accordance with the Mental Capacity Act 2005<br>• update additional information and drug interactions sections<br>• update for change of organisation from PHE to UKHSA<br>• web addresses hyperlinked into body text for clarity and consistency with other UKHSA PGDs | 12 October 2021 |

## 1. PGD Development

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

| Developed by: | Name | Signature | Date |
|---|---|---|---|
| **Pharmacist** (Lead Author) | Elizabeth Graham<br>Lead Pharmacist Immunisation Services, UKHSA |  | 13/10/2021 |
| **Doctor** | Mary Ramsay<br>Consultant Epidemiologist, UKHSA |  | 13/10/2021 |
| **Registered Nurse** (Chair of Expert Panel) | David Green<br>Nurse Consultant, UKHSA |  | 13/10/2021 |

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

### Expert Panel

| Name | Designation |
|---|---|
| Nicholas Aigbogun | Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA |
| Sarah Dermont | Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSEI |
| Ed Gardner | Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead |
| Jane Horsfall | Senior Policy Manager, Community Pharmacy, Strategy and Innovation Directorate, NHSEI |
| Michelle Jones | Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG |
| Jacqueline Lamberty | Lead Pharmacist Medicines Management Service, UKHSA |
| Jill Loader | Deputy Director, Pharmacy Commissioning, NHSEI |
| Vanessa MacGregor | Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA |
| Alison Mackenzie | Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSEI South (South West) |
| Gill Marsh | Principal Screening and Immunisation Manager, NHSEI (North West) |
| Lesley McFarlane | Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHSEI (Midlands) |
| Gul Root | Principal Pharmaceutical Officer, Department of Health & Social Care and National lead pharmacy public health. |
| Tushar Shah | Lead Pharmacy Advisor, NHSEI (London Region) |
| Conall Watson | Consultant Epidemiologist, UKHSA |

## 2. Organisational Authorisations

NHSEI accepts governance responsibility for 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.

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

| **Organisational approval (legal requirement)** | | | |
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| **Role** | **Name** | **Sign** | **Date** |
| Deputy Medical Director of Primary Care, NHSEI | Dr Raj Patel |  | 26.10.21 |

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 Section 7).

## 3. Characteristics of Staff

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| **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):<br>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)<br>• pharmacists currently registered with the General Pharmaceutical Council (GPhC)<br>• 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)<br>• dental hygienists and dental therapists registered with the General Dental Council<br>• optometrists registered with the General Optical Council.<br><br>Practitioners must also fulfil all the Additional requirements. |
| **Additional requirements** | Additionally, practitioners:<br>• 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)<br>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines as required by the community pharmacy seasonal influenza vaccination advanced service specification, the declaration of competence for vaccination services and in line with the National Minimum Standards and Core Curriculum for Immunisation Training. For further information on immunisation training during the COVID-19 pandemic see Guidance on immunisation training during the COVID-19 pandemic.<br>• must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs)<br>• 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 programme<br>• must be competent to undertake immunisation and to discuss issues related to seasonal influenza immunisation<br>• must be competent in the handling and storage of vaccines, and management of the 'cold chain' as outlined in the CPPE declaration of competence for vaccination services<br>• must be competent in the recognition and management of anaphylaxis<br>• must have access to the PGD and associated online resources.<br><br>**The practitioner must be authorised by name, under the current NHSEI authorised version of this PGD before working under its authority.** |
| **Continued training requirements**<br><br>Continued over page | Practitioners should ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD). |

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| **Continued training requirements** (continued) | Practitioners should be constantly alert to any subsequent recommendations from UKHSA and/or NHSEI, and other sources of medicines information.<br>Note: The most current national recommendations should be followed. However, if updated recommendations mean that to vaccinate the individual would be outside the scope of this PGD, the individual should be referred to their GP for vaccination. |

## 4. Clinical condition or situation to which this PGD applies

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| **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(s) and subsequent correspondence/publications from UKHSA and/or NHSEI. |
| **Criteria for inclusion** | In 2021/22, influenza vaccination should be offered at NHS expense to the following groups under the community pharmacy seasonal influenza vaccination advanced service:<br>• people aged 50 years or over (including those becoming age 50 years by 31 March 2022)<br>• adults aged from 18 years to under 50 years in a clinical risk group category listed in Chapter 19 of the Green Book such as:<br>  ○ chronic (long-term) respiratory disease, such as asthma (that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission), chronic obstructive pulmonary disease (COPD) or bronchitis<br>  ○ chronic heart disease, such as heart failure<br>  ○ chronic kidney disease at stage 3, 4 or 5<br>  ○ chronic liver disease<br>  ○ chronic neurological disease, such as Parkinson's disease or motor neurone disease,<br>  ○ learning disability<br>  ○ diabetes<br>  ○ asplenia or splenic dysfunction<br>  ○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)<br>  ○ morbidly obese with a BMI ≥ 40kg/$m^2$<br>  ○ pregnant women (including those women who become pregnant during the influenza season)<br>• adult household contacts (aged 18 years and over) 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<br>• adults (aged 18 years and over) 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 or university halls of residence<br>• adults (aged 18 years and over) 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<br>• primary care contractors (primary medical services, pharmaceutical services, primary dental services or general ophthalmic services) and their frontline staff, including locums (see Additional Information)<br>• health and social care staff (aged 18 years and over), employed by a registered residential care/nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable patients or clients who are at increased risk from exposure to influenza |

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| **Criteria for inclusion** continued | • health and care staff (aged 18 years and over), employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable patients or clients who are at increased risk from exposure to influenza<br>• health and social care workers employed through Direct Payments (personal budgets) and/or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to patients and service users. |
| **Criteria for exclusion**[1] | 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').<br><br>People who:<br>• are less than 18 years of age<br>• have had a confirmed anaphylactic reaction to a previous dose of the vaccine<br>• have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process[2] (other than ovalbumin – see Cautions)<br>• have received a complete dose of the recommended influenza vaccine for the current season<br>• 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** | Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration).<br><br>Individuals with a severe anaphylaxis to egg which has previously required intensive care can be immunised in any setting using an egg-free vaccine, for instance QIVc or QIVr. Individuals with less severe egg allergy can be immunised in any setting using an egg-free vaccine or an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to 0.06 micrograms for 0.5 ml dose). For details of the influenza vaccines available for the 2021/22 season and their ovalbumin content see Influenza vaccines: 2021 to 2022 flu season.<br><br>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. |
| **Action to be taken if the patient is excluded**<br><br>Continued over page | 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 and refer individuals to their GP for immunisation where appropriate.<br><br>Individuals under 18 years of age who are in a clinical risk group or |

[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 products SPC for details.

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| **Action to be taken if the patient is excluded** (continued) | otherwise eligible for influenza vaccination for the 2021/22 season should be referred to their GP or an appropriate local NHS service provider for immunisation.<br><br>In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged.<br><br>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'.<br><br>Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.<br><br>Document advice given and decision reached and inform patient's GP as appropriate. |
| **Arrangements for referral for medical advice** | Refer to individual's GP. |

## 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:<ul><li>adjuvanted quadrivalent influenza vaccine (aQIV), Fluad Tetra▼</li><li>cell-based quadrivalent influenza vaccine (QIVc), Flucelvax® Tetra▼</li><li>egg-grown quadrivalent influenza vaccine (QIVe)</li><li>recombinant quadrivalent influenza vaccine (QIVr), Supemtek▼</li></ul>Note: This PGD does not include high-dose quadrivalent influenza vaccine (QIV-HD) or trivalent influenza vaccines as these vaccines are not eligible for re-imbursement under the NHS influenza vaccination programme in 2021/22.<br><br>The vaccines that are available for the 2021 to 2022 influenza immunisation programme are listed in the document Influenza vaccines: 2021 to 2022 flu season.<br><br>Some influenza vaccines are restricted for use in particular age groups. The SPC for individual products should always be referred to.<br><br>Summary table of which influenza vaccines to offer (by age)<table><tr><th>Age</th><th>Recommended influenza vaccine for adults</th></tr><tr><td>18 years to under 65 years</td><td>Offer QIVc or QIVr.<br>Or, if QIVc or QIVr are not available, offer QIVe.</td></tr><tr><td>65 years and over[3]</td><td>Offer aQIV.<br>Or, if aQIV is not available, offer QIVc or QIVr.<br>It is recommended that aQIV is offered ‘off-label’ to those who become 65 years of age before 31 March 2022 (see Off-label use section).</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.<br><br>QIVe vaccine from Viatris (formerly Mylan) is black triangle.<br><br>This information was accurate at the time of writing. See product SPCs, available from the electronic medicines compendium website, for indication of current black triangle status.</td></tr>
<tr><td>Off-label use<br><br>Continued over page</td><td>The aQIV is licensed for administration to individuals aged 65 years and over. It may be administered under this PGD to 64-year olds turning 65 years of age by 31 March 2022 in accordance with the recommendations for the national influenza immunisation programme for 2021/22.<br><br>Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with</td></tr>
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[3] JCVI recommended use of QIV-HD in this age group but this is not currently available in the UK market.

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| **Off-label use** (continued) | these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.<br><br>Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.<br><br>Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this PGD, unless permitted off-label administration is detailed above. Refer to products' SPCs, available from the electronic medicines compendium website, and the table of Influenza vaccines: 2021 to 2022 flu season for more information. |
| **Route / method of administration**<br><br>Continued over page | Administer by intramuscular injection, preferably into the deltoid region of the upper arm.<br><br>Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy.<br><br>Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.<br><br>Influenza vaccines licensed for both intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. Subcutaneous administration is covered by this PGD where the practitioner is trained and competent in administration via the subcutaneous route. Note: QIVc (Flucelvax® Tetra▼), QIVr (Supemtek▼) and aQIV (Fluad Tetra▼) are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD.<br><br>When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations.<br><br>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.<br><br>Shake vaccine before administration. |

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| **Route / method of administration** (continued) | Inspect visually prior to administration and ensure appearance is consistent with the description in the SPC for the vaccine being administered.<br><br>The SPC for each vaccine provides further guidance on administration and is 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 2021 to 31 March 2022). |
| **Duration of treatment** | Single 0.5ml dose for the current annual flu season. |
| **Quantity to be supplied / 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.<br><br>Should centrally procured vaccines for patients aged 18 years and over be made available, they should be ordered and used in accordance with any related guidance. |
| **Storage** | Store between +2°C to +8°C. Do not freeze.<br>Store in original packaging in order to protect from light.<br><br>In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance. |
| **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 guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013). |
| **Drug interactions** | Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.<br><br>Because of the absence of data on co-administration of Shingrix® vaccine with adjuvanted influenza vaccine, administration should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. Where individuals require rapid protection or are likely to be lost to follow up, administration at an interval of less than 7 days may still be considered, which may include coadministration at clinical services that offer both vaccines.<br><br>Inactivated influenza vaccination may be given at the same time as other vaccines (see Route / method of administration).<br><br>A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, patients should 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, although separating the vaccines by a day or two will avoid confusion over systemic side effects. |

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| **Drug interactions** (continued) | A detailed list of drug interactions associated with inactivated influenza vaccine 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.<br><br>Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur.<br><br>A higher incidence of mild post-immunisation reactions has been reported with adjuvanted compared to non-adjuvanted influenza vaccines.<br><br>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.<br><br>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. |
| **Reporting procedure of adverse reactions** | Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store.<br><br>QIVe vaccine from Viatris (formerly Mylan), QIVc, QIVr and aQIV are black triangle. Therefore, any suspected adverse reactions to these products should be reported via the Yellow Card Scheme.<br><br>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. |
| **Written information to be given to patient or carer** | Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. |
| **Patient advice / follow up treatment**<br><br>Continued over page | 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.<br><br>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.<br><br>Inform the individual/carer of possible side effects and their management.<br><br>The individual/carer should be advised when and where to seek appropriate advice in the event of an adverse reaction. |

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| **Patient advice / follow up treatment** (continued) | In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed.<br><br>Advise the individual/carer when a subsequent vaccine dose is due, such as a single immunisation for each annual influenza season.<br><br>If the individual is eligible for COVID-19 vaccination or PPV23 on the NHS and has not received it, they should be signposted to their GP or an appropriate provider to receive the vaccine on the NHS. |
| **Special considerations / 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.<br><br>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.<br><br>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.<br><br>For the avoidance of doubt primary care contractors (primary medical services, pharmaceutical services, primary dental services or general ophthalmic services) and their frontline staff are those involved in patient-facing frontline provision of NHS primary care services and includes non-clinical reception and counter staff who play an integral part in patient-facing care on a day-to-day basis in primary care settings. Any primary care contractors and their staff not involved in patient-facing frontline provision of NHS primary care services are not included in the definition of frontline staff. |
| **Records**<br><br>Continued over page | Record:<br>• that valid informed consent was given<br>• name of individual, address, date of birth and GP practice with whom the individual is registered (or record where an individual is not registered with a GP and that appropriate advice has been given)<br>• eligible/clinical risk group indication for immunisation<br>• name of immuniser<br>• name and brand of vaccine<br>• date of administration<br>• dose, form and route of administration of vaccine<br>• quantity administered<br>• batch number and expiry date<br>• anatomical site of vaccination<br>• advice given, including advice given if not vaccinated<br>• details of any adverse drug reactions and actions taken<br>• supplied via PGD<br><br>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.<br><br>All records should be clear, legible, contemporaneous and in line with the community pharmacy seasonal influenza immunisation advanced service specification. |

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| **Records** (continued) | 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.<br><br>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.<br><br>For pregnant women, also record immunisation in the hand-held maternity record (if available).<br><br>Records of all individuals receiving treatment under this PGD should also be kept for audit purposes and post payment verification. |

## 6. Key References

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| **Key references** | **Inactivated influenza vaccination**<br>• Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 29 October 2020 https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19<br>• Collection: Annual Flu Programme. Updated 12 October 2021 https://www.gov.uk/government/collections/annual-flu-programme<br>• Community Pharmacy Seasonal Influenza Vaccine Service https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service/<br>• The national flu immunisation programme 2021 to 2022: supporting letter. Published 17 July 2021 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan<br>• Influenza vaccines: 2021 to 2022 flu season https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content<br>• Declaration of competence for vaccination services https://www.cppe.ac.uk/services/declaration-of-competence<br>• Summary of Product Characteristics www.medicines.org.uk<br>**General**<br>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health. 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/<br>• 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<br>• 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<br>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017 https://www.nice.org.uk/guidance/mpg2<br>• 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<br>• UKHSA Guidance on immunisation training during the COVID-19 pandemic. 26 June 2020 https://www.gov.uk/government/publications/immunisation-training-guidance-during-the-covid-19-pandemic/guidance-on-immunisation-training-during-the-covid-19-pandemic<br>• UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation<br>• PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors |

## 7. Practitioner authorisation sheet

**Pharmacy Influenza Vaccination PGD v09.00 Valid from: 21/10/2021 Expiry: 31/03/2022**

### 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 |
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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.