



PHE publications gateway number: **GW-497**

PATIENT GROUP DIRECTION (PGD)

Administration of inactivated influenza vaccine to individuals in accordance with the national immunisation programme¹ for active immunisation against influenza.

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 2.²

Reference no: Inactivated Influenza PGD
Version no: v07.00
Valid from: 1 September 2019
Review date: 1 April 2020
Expiry date: 31 March 2020

Public Health England has developed this PGD to facilitate the delivery of publicly-funded immunisation 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)³. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH [HMR2012 SCHEDULE 16 Part 2](#).**

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

Operation of this PGD is the responsibility of commissioners and service providers.

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 PHE PGD templates for authorisation can be found from:

<https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd>

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

¹ This PGD covers NHS commissioned services. This PGD does not cover the provision of occupational health schemes or peer-to-peer influenza immunisation (see <https://www.sps.nhs.uk/articles/pgds-and-occupational-health-schemes/>).

² This PGD is not relevant to the national community pharmacy seasonal influenza vaccination advanced service which has its own PGD (see Pharmacy Influenza Vaccination PGD).


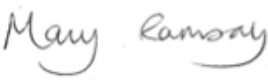

³ This includes any relevant amendments to legislation (such as [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).
Inactivated Influenza PGD v07.00 Valid from: 01/09/2019 Expiry: 31/03/2020

Change history

| Version number | Change details | Date |
|----------------|--|------------------|
| V01.00 | New PHE PGD template | 18 August 2015 |
| V02.00 | See earlier version of this PGD for change details. | 09 August 2016 |
| V03.00 | See earlier version of this PGD for change details. | 04 July 2017 |
| V04.00 | See earlier version of this PGD for change details. | 17 August 2017 |
| V05.00 | See earlier version of this PGD for change details. | 01 November 2017 |
| V06.00 | <p>PHE IM Influenza PGD amended to:</p> <ul style="list-style-type: none"> • include additional healthcare practitioners in Section 3 • include adjuvanted trivalent influenza vaccine Fludax[®] and related information regarding administration of this product • provide further guidance on route of administration for individuals with bleeding disorders or on anticoagulants • refer to vaccine incident guidelines in off-label and storage sections • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates | 10 August 2018 |
| V07.00 | <p>PHE IM Influenza PGD amended to:</p> <ul style="list-style-type: none"> • remove inclusion criteria relating to the immunisation of health and social care workers as part of an organisation's occupational health obligation and refer to the national written instruction template • include vaccines for the 2019/20 season, including cell-based quadrivalent influenza vaccine (QIVc) • update cautions for egg allergy and include use of QIVc which is egg-free • include reference to the Directed Enhanced Service and offer to morbidly obese adults from 16 years of age • include reference to the Flu Vaccinations: Supporting people with learning disabilities guidance from PHE | 8 May 2019 |

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

| Developed by: | Name | Signature | Date |
|--|--|--|------------|
| Pharmacist (Lead Author) | Elizabeth Graham Lead Pharmacist Immunisation Services, Immunisation and Countermeasures, PHE |  | 05/06/2019 |
| Doctor | Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE |  | 04/06/2019 |
| Registered Nurse (Chair of Expert Panel) | David Green Nurse Consultant, Immunisation and Countermeasures, PHE |  | 24/05/2019 |

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

Expert Panel

| Name | Designation |
|---------------------|--|
| Ed Gardner | Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead |
| Michelle Jones | Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG |
| Jacqueline Lamberty | Lead Pharmacist Medicines Management Services, Public Health England |
| Vanessa MacGregor | Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team |
| Alison Mackenzie | Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England and NHS Improvement South (South West) |
| Gill Marsh | Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement North West (Lancashire and South Cumbria Screening and immunisation Team) |
| Lesley McFarlane | Screening and Immunisation Co-ordinator, Public Health England / NHS England and NHS Improvement Midlands (Leicestershire, Lincolnshire and Northamptonshire) |
| Sally Millership | Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team |
| Richard Pebody | Consultant Medical Epidemiologist, Immunisation and Countermeasures, Public Health England |
| Tushar Shah | Pharmacy Advisor, NHS England and NHS Improvement London Region |
| Sharon Webb | Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England |


2. Organisational authorisations

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

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

NHS England Hampshire and Thames Valley (HTV) 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 HTV directly commissioned immunisation services. In addition, the PGD may be adopted by provider organisations (providing NHS immunisation and vaccination services) working within the HTV geography. Where this occurs, provider organisations should have this PGD signed off by their governance lead prior to use. Provider organisation staff will be expected to follow local policies and procedures. |
| Limitations to authorisation |
| None. |

| Organisational approval (legal requirement) | | | |
|--|--------------|--|-------------|
| Role | Name | Sign | Date |
| Medical Directoror | Shahed Ahmad |  | 29/7/19 |

| Additional signatories according to locally agreed policy | | | |
|--|-------------|-------------|-------------|
| Role | Name | Sign | Date |
| | | | |
| | | | |
| | | | |
| | | | |

Local enquiries regarding the use of this PGD may be directed to england.southcentral-pgd@nhs.net

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be

used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

| | |
|--|---|
| <p>Qualifications and professional registration</p> | <p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to the national community pharmacy seasonal influenza vaccination advanced service nor privately provided community pharmacy services) • paramedics, physiotherapists and radiographers currently registered with the Health and Care Professions Council (HCPC) <p>The practitioners above must also fulfil the Additional requirements detailed below.</p> <p>Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p> |
| <p>Additional requirements</p> | <p>Additionally practitioners:</p> <ul style="list-style-type: none"> • 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/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • 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 • 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 <p>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</p> |
| <p>Continued training requirements</p> | <p>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).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information.</p> <p>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.</p> |

4. Clinical condition or situation to which this PGD applies

| | |
|---|---|
| <p>Clinical condition or situation to which this PGD applies</p> | <p>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', the annual flu letter and subsequent correspondence/publications from PHE and/or NHS England.</p> <p>Note: This PGD covers NHS commissioned services. This PGD does not cover the provision of occupational health schemes or peer-to-peer influenza immunisation (See NHS Specialist Pharmacy Service 'Written instruction' for registered nurses to administer inactivated seasonal influenza vaccine as part of an occupational health scheme, which may include peer-to-peer immunisation').</p> |
| <p>Criteria for inclusion</p> <p>Continued over page Criteria for inclusion (continued)</p> | <p>In 2019/20, flu vaccinations should be offered to the following groups:</p> <ul style="list-style-type: none"> • people aged 65 years or over⁴ • people aged from 6 months to less than 65 years of age in a clinical risk group (see Appendix A) such as: <ul style="list-style-type: none"> ○ chronic (long-term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis ○ chronic heart disease, such as heart failure ○ chronic kidney disease at stage 3, 4 or 5 ○ chronic liver disease ○ chronic neurological disease, such as Parkinson's disease or motor neurone disease, or learning disability ○ diabetes ○ asplenia or splenic dysfunction ○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment) ○ morbidly obese adults (aged from 16 years) with a BMI > 40kg/m² ○ all pregnant women (including those women who become pregnant during the flu season) • 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 or university halls of residence • people 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 • 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 • health and social care staff, employed by a registered residential care/nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable⁵ patients/clients who are at increased risk from exposure to influenza |

⁴ including those becoming age 65 years by 31 March 2020

⁵ Vulnerable means those patients/clients in a clinical risk group for flu or who are aged 65 years and over

| | |
|---|--|
| | <ul style="list-style-type: none"> health and care staff, employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable⁵ patients/clients who are at increased risk from exposure to influenza |
| Criteria for exclusion⁶ | <p>Individuals for whom no valid consent has been received (for further information on consent see DH Reference guide to consent for examination or treatment).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> are less than 6 months of age are aged 2 years to under 18 years for whom live attenuated influenza vaccine (LAIV) is NOT contraindicated (or not otherwise unsuitable, for instance due to the route or religious acceptance of porcine gelatin content) and is available. Note: LAIV should be given to those aged 2 to under 18 years 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 process⁷ (other than ovalbumin – see Cautions) are less than 9 years of age and have had a severe anaphylactic reaction to egg which has previously required intensive care 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 group category listed in Chapter 19 of the ‘The Green Book’ who should, in the first season they are vaccinated against influenza, receive a second dose of an appropriate influenza vaccine at least 4 weeks after the first dose are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) |
| Cautions including any relevant action to be taken | <p>Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration).</p> <p>Individuals from 9 years of age with a severe anaphylaxis to egg which has previously required intensive care can be immunised in any setting using an egg-free vaccine, Flucelvax® Tetra▼ (QIVc), which is licenced for use in this age group. Individuals with less severe egg allergy can be immunised in any setting using an egg-free vaccine or inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to 0.06 micrograms in a 0.5 ml dose). For details of the influenza vaccines available for the 2019/20 season and their ovalbumin content see Influenza vaccine ovalbumin content. LAIV remains the preferred vaccine for children with a previous anaphylaxis to egg and the above advice only applies to children who also have another condition which contraindicates LAIV.</p> <p>Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to</p> |
| Continued over page | |

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 barium sulphate, beta-propiolactone, cetyltrimethylammonium bromide (CTAB), formaldehyde, gentamicin, kanamycin, neomycin, octoxinol-9, polymyxin, polysorbate 80, sodium deoxycholate. Check the vaccine products SPC for details.

| | |
|--|--|
| <p>Cautions including any relevant action to be taken (continued)</p> | <p>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.</p> |
| <p>Action to be taken if the patient is excluded</p> | <p>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.</p> <p>Individuals under 9 years of age with severe anaphylaxis to egg which has previously required intensive care should be referred, as per the Green Book guidelines, to a specialist for assessment with regard to receiving immunisation in hospital, preferably with LAIV.</p> <p>In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required, as a PSD may be indicated.</p> <p>In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.</p> |
| <p>Action to be taken if the patient or carer declines treatment</p> | <p>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).</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Document advice given and the decision reached.</p> <p>In a GP practice setting, inform or refer to the GP as appropriate.</p> |
| <p>Arrangements for referral for medical advice</p> | <p>As per local policy.</p> |

5. Description of treatment

| <p>Name, strength & formulation of drug</p> | <p>Inactivated influenza vaccine suspension in a pre-filled syringe, including:</p> <ul style="list-style-type: none"> • egg-grown quadrivalent influenza vaccine (QIVe) • cell-based quadrivalent influenza vaccine (QIVc), Flucelvax® Tetra ▼ • adjuvanted trivalent influenza vaccine (aTIV), Fludax® <p>Note: This PGD does not include high-dose trivalent influenza vaccine (TIV-HD) or standard dose non-adjuvanted trivalent influenza vaccine (TIVe) as these vaccines are not eligible for reimbursement under the NHS influenza vaccination programme in 2019/20.</p> <p>A list of the influenza vaccines available in the UK was published in the annual flu letter for England and subsequent updates can be found in Vaccine Update.</p> <p>Recommended vaccine choice</p> <table border="1" data-bbox="566 817 1465 1944"> <thead> <tr> <th data-bbox="566 817 721 875">Age</th> <th data-bbox="721 817 1465 875">Recommended influenza vaccine</th> </tr> </thead> <tbody> <tr> <td data-bbox="566 875 721 1093">6 months to less than 2 years</td> <td data-bbox="721 875 1465 1093">Offer a suitable QIVe supplied centrally via ImmForm. Note: LAIV, QIVc and aTIV are not licensed in this age group. Some QIVe products are not licensed in this age group, see product SPCs, and obtain appropriate supplies via ImmForm.</td> </tr> <tr> <td data-bbox="566 1093 721 1624">2 years to under 18 years of age</td> <td data-bbox="721 1093 1465 1624">Offer LAIV supplied centrally via ImmForm (see LAIV PGD). Offer a suitable QIVe supplied centrally via ImmForm to individuals under 18 years of age in clinical risk groups, or otherwise eligible under this PGD, for whom LAIV is contraindicated (or is otherwise unsuitable, for instance due to religious acceptance of porcine gelatin content). Note: QIVc is only licensed for individuals from 9 years of age and will not be centrally supplied. The aTIV is not licensed in this age group. Some QIVe products are not licensed in younger age groups, see product SPCs, and obtain appropriate QIVe supplies via ImmForm.</td> </tr> <tr> <td data-bbox="566 1624 721 1765">18 years to under 65 years</td> <td data-bbox="721 1624 1465 1765">Offer either QIVe or QIVc. Note: LAIV and aTIV are not licensed in this age group.</td> </tr> <tr> <td data-bbox="566 1765 721 1944">65 years and over⁴</td> <td data-bbox="721 1765 1465 1944">Offer either QIVc or aTIV (see Off-label use section). Note: LAIV is not licensed in this age group. QIVe is not recommended in this age group as QIVc and aTIV are preferable.</td> </tr> </tbody> </table> | Age | Recommended influenza vaccine | 6 months to less than 2 years | Offer a suitable QIVe supplied centrally via ImmForm. Note: LAIV, QIVc and aTIV are not licensed in this age group. Some QIVe products are not licensed in this age group, see product SPCs, and obtain appropriate supplies via ImmForm. | 2 years to under 18 years of age | Offer LAIV supplied centrally via ImmForm (see LAIV PGD). Offer a suitable QIVe supplied centrally via ImmForm to individuals under 18 years of age in clinical risk groups, or otherwise eligible under this PGD, for whom LAIV is contraindicated (or is otherwise unsuitable, for instance due to religious acceptance of porcine gelatin content). Note: QIVc is only licensed for individuals from 9 years of age and will not be centrally supplied. The aTIV is not licensed in this age group. Some QIVe products are not licensed in younger age groups, see product SPCs, and obtain appropriate QIVe supplies via ImmForm. | 18 years to under 65 years | Offer either QIVe or QIVc. Note: LAIV and aTIV are not licensed in this age group. | 65 years and over ⁴ | Offer either QIVc or aTIV (see Off-label use section). Note: LAIV is not licensed in this age group. QIVe is not recommended in this age group as QIVc and aTIV are preferable. |
|--|---|-----|-------------------------------|-------------------------------|--|----------------------------------|---|----------------------------|---|--------------------------------|--|
| Age | Recommended influenza vaccine | | | | | | | | | | |
| 6 months to less than 2 years | Offer a suitable QIVe supplied centrally via ImmForm. Note: LAIV, QIVc and aTIV are not licensed in this age group. Some QIVe products are not licensed in this age group, see product SPCs, and obtain appropriate supplies via ImmForm. | | | | | | | | | | |
| 2 years to under 18 years of age | Offer LAIV supplied centrally via ImmForm (see LAIV PGD). Offer a suitable QIVe supplied centrally via ImmForm to individuals under 18 years of age in clinical risk groups, or otherwise eligible under this PGD, for whom LAIV is contraindicated (or is otherwise unsuitable, for instance due to religious acceptance of porcine gelatin content). Note: QIVc is only licensed for individuals from 9 years of age and will not be centrally supplied. The aTIV is not licensed in this age group. Some QIVe products are not licensed in younger age groups, see product SPCs, and obtain appropriate QIVe supplies via ImmForm. | | | | | | | | | | |
| 18 years to under 65 years | Offer either QIVe or QIVc. Note: LAIV and aTIV are not licensed in this age group. | | | | | | | | | | |
| 65 years and over ⁴ | Offer either QIVc or aTIV (see Off-label use section). Note: LAIV is not licensed in this age group. QIVe is not recommended in this age group as QIVc and aTIV are preferable. | | | | | | | | | | |
| <p>Legal category</p> | <p>Prescription only medicine (POM).</p> | | | | | | | | | | |
| <p>Black triangle ▼</p> | <p>QIVe and QIVc products are black triangle.</p> | | | | | | | | | | |

| | |
|---|---|
| <p>Off-label use</p> | <p>Fluad® (aTIV) 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 2020 in accordance with the recommendations for the national influenza immunisation programme for 2019/20.</p> <p>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 these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p> <p>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 at www.medicines.org.uk and Appendix E of the annual flu letter) for more information.</p> |
| <p>Route / method of administration</p> <p>Continued over page</p> | <p>Administer by intramuscular injection, preferably into deltoid region of the upper arm. The anterolateral aspect of the thigh is the preferred site for infants under 1 year old.</p> <p>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.</p> <p>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/parent/carer should be informed about the risk of haematoma from the injection.</p> <p>Influenza vaccines licensed for intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. Note: Fluarix® Tetra ▼, Flucelvax® Tetra ▼ and Fluad® are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD.</p> |

| | |
|--|--|
| <p>Route / method of administration (continued)</p> | <p>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.</p> <p>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 aTIV, Fluad®, needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs.</p> <p>Shake vaccine before administration.</p> <p>Inspect visually prior to administration and ensure appearance is consistent with the description in the products SPC.</p> <p>The SPCs provide further guidance on administration and are available from the electronic Medicines Compendium website: www.medicines.org.uk</p> |
| <p>Dose and frequency of administration</p> | <p>Single 0.5ml dose to be administered for the current annual flu season.</p> <p>Children in a clinical risk group aged 6 months to less than 9 years old 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).</p> <p>JCVI has advised that when a choice of either a 0.25ml or 0.5ml dose is indicated in the SPC, the 0.5ml dose of inactivated influenza vaccine should be given to individuals from age 6 months because there is evidence that this dose is effective in young children.</p> |
| <p>Duration of treatment</p> | <p>Single 0.5ml dose for the current annual flu season (1 September 2019 to 31 March 2020).</p> <p>Children aged 6 months to less than 9 years old in a clinical risk group who have not received influenza vaccine previously should be offered a second dose of the vaccine at least 4 weeks later.</p> |
| <p>Quantity to be supplied / administered</p> | <p>Single dose of 0.5ml per administration.</p> |
| <p>Supplies</p> | <p>Given that some influenza vaccines are restricted for use in particular age groups, the SPCs for individual products should always be referred to when ordering vaccines to ensure that they can be given appropriately to particular age groups.</p> <p>Supplies for administration to adults should be ordered from the influenza vaccine manufacturers/wholesalers as in previous years.</p> <p>For children under 18 years of age, where LAIV is medically contraindicated or otherwise unsuitable, a QIVe will be supplied. These vaccines should be ordered as per the usual mechanisms for the routine childhood immunisation programme.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).</p> |

| | |
|---|--|
| Storage | <p>Store at +2°C to +8°C. Do not freeze. Store in original packaging in order to protect from light.</p> <p>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.</p> |
| Disposal | <p>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 regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).</p> |
| Drug interactions | <p>Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.</p> <p>Inactivated influenza vaccine may be given at the same time as other vaccines (See Route / method of administration).</p> <p>A detailed list of drug interactions is available in the SPC for each vaccine, which are available from the electronic Medicines Compendium website: www.medicines.org.uk</p> |
| Identification & management of adverse reactions | <p>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.</p> <p>Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur.</p> <p>A higher incidence of mild post-immunisation reactions has been reported with aTIV compared to non-adjuvanted influenza vaccines.</p> <p>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.</p> <p>A detailed list of adverse reactions is available in the SPC for each vaccine, which are available from the electronic Medicines Compendium website: www.medicines.org.uk</p> |
| Reporting procedure of adverse reactions | <p>Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk</p> <p>QIVc and QIVe are black triangle. Therefore, any suspected adverse reactions should be reported via the Yellow Card Scheme.</p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p> |

| | |
|--|--|
| Written information to be given to patient or carer | Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. |
| Patient advice / follow up treatment | <p>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.</p> <p>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.</p> <p>Inform the individual/parent/carer of possible side effects and their management.</p> <p>The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>When applicable, advise the individual/parent/carer when to return for vaccination or when a subsequent vaccine dose is due.</p> |
| Special considerations / additional information | <p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination.</p> <p>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.</p> <p>For children under the age of 16 years, those assessed as Gillick competent can self-consent (for further information on consent see DH Reference guide to consent for examination or treatment).</p> <p>In accordance with Appendix A and the Seasonal Influenza Directed Enhanced Service, morbidly obese adults (aged from 16 years) with a BMI > 40kg/m² should be offered influenza immunisation.</p> <p>Individuals with learning disabilities may require reasonable adjustments to support vaccination (see https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities). A PSD may be required.</p> <p>The licensed ages for the 2019/20 season influenza vaccines are:</p> <ul style="list-style-type: none"> • QIVe split virion inactivated vaccines are licensed from 6 months of age • QIVe surface antigen inactivated vaccines are licenced from 3 years of age • QIVc, Flucelvax® Tetra ▼, is licenced from 9 years of age • aTIV, Fluad®, is licensed for individuals aged 65 years and over (see Off-label section) • LAIV, Fluenz® Tetra, is licensed from 24 months to less than 18 years (see LAIV PGD) |
| Records Continued over page | <p>Record:</p> <ul style="list-style-type: none"> • 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 |

Records
(continued)

- dose, form and route of administration of vaccine
- quantity administered
- batch number and expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- supplied via PGD

Records should be signed and dated (or password controlled immunisers record 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, a record of vaccination should be 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 maternity record (if available).

A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

| | |
|---|---|
| <p>Key references</p> <p>Continued over page</p> | <p>Inactivated influenza vaccination</p> <ul style="list-style-type: none">• Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 23 April 2019. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book• Collection: Annual Flu Programme. Updated 22 March 2019. https://www.gov.uk/government/collections/annual-flu-programme• The national flu immunisation programme 2019 to 2020: supporting letter. Published 22 March 2019. https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan• Directed Enhanced Service Specification, Seasonal influenza and pneumococcal polysaccharide vaccination programme 2019/20. https://www.england.nhs.uk/publication/gp-contract-2019-20-nhs-england-enhanced-service-specifications/• Influenza vaccine ovalbumin content. https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content• Live attenuated influenza vaccine (LAIV) PGD https://www.gov.uk/government/publications/influenza-vaccine-fluenz-tetra-patient-group-direction-pgd-template• Written instruction for the administration of seasonal ‘flu vaccination. NHS Specialist Pharmacy Service. 21 May 2019. https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/• Summary of Product Characteristics www.medicines.org.uk• Flu Vaccinations: Supporting people with learning disabilities. Updated 25 September 2018. https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities <p>General</p> <ul style="list-style-type: none">• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources• PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation |
|---|---|

| | |
|--------------------------------------|---|
| Key references (continued) | <ul style="list-style-type: none">• PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors• Reference guide to consent for examination or treatment, Department of Health, published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition |
|--------------------------------------|---|

8. Practitioner authorisation sheet

Inactivated Influenza PGD v07.00 Valid from: 01/09/2019 Expiry: 31/03/2020

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 patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions 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 Patient Group Direction 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 NHS England Hampshire and Thames Valley 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.

APPENDIX A

Clinical risk groups who should receive the influenza immunisation

Influenza vaccine should be offered to people in the clinical risk categories set out below.

| Clinical risk category | Examples (this list is not exhaustive and individuals may be referred for decisions based on clinical judgement) |
|---|--|
| Chronic respiratory disease | Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children who have previously been admitted to hospital for lower respiratory tract disease. |
| Chronic heart disease | Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease. |
| Chronic kidney disease | Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation. |
| Chronic liver disease | Cirrhosis, biliary atresia, chronic hepatitis. |
| Chronic neurological disease (included in the DES directions for Wales) | Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers). Clinicians should offer immunisation, based on individual assessment, to clinically vulnerable individuals including those with cerebral palsy, learning disabilities, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability. |
| Diabetes | Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes. |
| Immunosuppression (see contraindications and precautions section on live attenuated influenza vaccine) | Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement disorder). Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kg, a dose of 1mg or more per kg per day. It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immunocompromised patients may have a suboptimal immunological response to the vaccine. |
| Asplenia or dysfunction of the spleen | This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction. |
| Pregnant women | Pregnant women at any stage of pregnancy (first, second or third trimesters). |
| Morbid obesity (class III obesity) | Adults with a Body Mass Index ≥ 40 kg/m ² |