Public Health England

PHE publications gateway number: GW-1533

Inactivated influenza vaccine Patient Group Direction (PGD)

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

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

Reference no:	Inactivated Influenza PGD
Version no:	v08.00
Valid from:	1 September 2020
Review date:	1 April 2021
Expiry date:	31 March 2021

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)[2]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

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

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

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

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of 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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: ENGLAND.SCRIMMS@nhs.net the Derbyshire and Nottinghamshire health/screening and immunisation team.

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

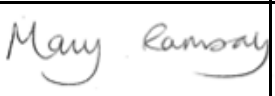
[2] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178 and 2015 No.323).

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	See earlier version of this PGD for change details.	10 August 2018
V07.00	PHE IM Influenza PGD amended to: • 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
V08.00	PHE IM Influenza PGD amended to: • extend the characteristics of staff to include all registered practitioners legally able to work under PGD • 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, subject to vaccine supply, extension of the programme to individuals from 50 years of age and children in routine age cohorts unable to receive LAIV • update the table of recommended inactivated influenza vaccines for the 2020/21 season • update supplies section • remove reference to Fluad® brand which will not be supplied to UK this season and remove black triangle from Fluarix® Tetra • 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 • update additional information section • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	24 August 2020

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		25/08/2020
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		25/08/2020
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		25/08/2020

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
Nicholas Aigbogun	Consultant in Communicable Disease Control, Public Health England
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
Jamie Lopez Bernal	Consultant Medical Epidemiologist, Immunisation and Countermeasures, 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 (South West) / 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)
Lesley McFarlane	Screening and Immunisation Co-ordinator, Public Health England / NHS England and NHS Improvement Midlands (Central Midlands)
Tushar Shah	Lead 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 and NHS Improvement - Midlands authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Primary Care services and all organisations commissioned to, or contracted by, NHS England and NHS Improvement – Midlands to provide immunisation services across Derbyshire and Nottinghamshire. Each provider organisation using this PGD should formally adopt it via a signature from the provider's authorised governance lead/s or lead practitioner.
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director of Primary Care and Public Health Commissioning NHS England and NHS Improvement: Midlands	**Trish Thompson**		**26.08.2020**

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

Local enquiries regarding the use of this PGD may be directed to ENGLAND.SCRIMMS@nhs.net the Derbyshire and Nottinghamshire health/screening and immunisation team.

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

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

3. Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to the national community pharmacy seasonal influenza vaccination advanced service nor privately provided community pharmacy services) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council. Practitioners must also fulfil all the Additional requirements. Check Section 2 Limitations to authorisation to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/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. For further information on immunisation training during the COVID-19 pandemic see Guidance on immunisation training during the COVID-19 pandemic and Flu immunisation training recommendations • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**

Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and NHS Improvement and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Inactivated influenza vaccine is indicated for the active immunisation of individuals for the prevention of influenza infection, in accordance with the national immunisation programme and recommendations given in Chapter 19 of the Immunisation Against Infectious Disease: the 'Green Book', annual flu letters and subsequent correspondence/publications from PHE and/or NHS England and NHS Improvement. 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 template for the administration of inactivated seasonal influenza vaccine as part of an occupational health scheme, which may include peer-to-peer immunisation').
Criteria for inclusion Continued over page	In 2020/21, influenza vaccine should be offered to the following groups: • people aged 65 years or over[3] • people aged from 6 months to less than 65 years of age in a clinical risk group (see Appendix A) such as: • 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 • 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/m^2 • 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

[3] including those becoming age 65 years by 31 March 2021

Criteria for inclusion (continued)	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 those on the NHS Shielded Patient List, or immunocompromised individuals, specifically individuals who expect to share living accommodation with a shielded patient 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 vulnerable[4] patients/clients who are at increased risk from exposure to influenza • health and care staff, employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable[4] patients/clients who are at increased risk from exposure to influenza • 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. Additionally, in 2020/21, subject to sufficient inactivated influenza vaccine supplies being available nationally and contractual negotiation, the offer of inactivated influenza vaccine may be extended to: • children eligible for the Routine Childhood Seasonal Influenza Vaccination Programme who do not accept live attenuated influenza vaccine (LAIV) due to porcine gelatine content (see Additional Information for when vaccine may be administered to these individuals). • people aged: ○ 64 to 65 years ○ 63 to 64 years ○ 62 to 63 years ○ 61 to 62 years ○ 60 to 61 years ○ 59 to 60 years ○ 58 to 59 years ○ 57 to 58 years ○ 56 to 57 years ○ 55 to 56 years ○ 54 to 55 years ○ 53 to 54 years ○ 52 to 53 years ○ 51 to 52 years ○ 50 to 51 years The date from which individuals in these additional cohorts may be vaccinated will be formally announced later in the flu season. A copy of this announcement will be made available at: https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan. Following this announcement, confirmation that the use of this PGD may be extended to children in routine age cohorts who do not accept porcine gelatin, or to a
Continued over page	

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

Criteria for inclusion (continued)	specified year group or groups under 65 years of age, will be provided, with authorisation from the national PGD clinical signatories, and will be published at: https://www.gov.uk/government/publications/intramuscular-inactivated-influenza-vaccine-patient-group-direction-pgd-template
Criteria for exclusion[5]	Individuals for whom no valid consent has been received (for further information on consent see Reference guide to consent for examination or treatment). Individuals who: • are less than 6 months of age • are aged 2 years to under 18 years for whom live attenuated influenza vaccine (LAIV) is NOT contraindicated (or not otherwise unsuitable, for instance due to the route or non-acceptance of porcine gelatine 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 process[6] (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 'Green Book' who should, in the first season they are vaccinated against influenza, receive a second dose of an appropriate influenza vaccine at least 4 weeks after the first dose • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken Continued over page	Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). LAIV remains the preferred vaccine for children with a previous anaphylaxis to egg and the below advice only applies to children who are otherwise unable to receive LAIV. 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 licensed 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 2020/21 season and their ovalbumin content see Influenza vaccines: 2020 to 2021 flu season. Syncope (fainting) can occur following, or even before, any

[5] 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

[6] Residues from the manufacturing process may include beta-propiolactone, cetyltrimethylammonium bromide (CTAB), formaldehyde, gentamicin, kanamycin, neomycin, octoxinol-9, polymyxin, polysorbate 80, sodium deoxycholate. Check the vaccine products SPC for details.

Cautions including any relevant action to be taken (continued)	vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Action to be taken if the patient is excluded	The risk to the individual of not being immunised must be taken into account. The indications for flu vaccination are not exhaustive, and the healthcare practitioner should consider the risk of flu exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from flu itself. Where appropriate, such individuals should be referred, or a PSD obtained for immunisation. 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. In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Document the reason for exclusion and any action taken in the individual's clinical records. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. Inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration (see Additional Information). Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy.

5. Description of treatment

<table>
<tr><td>Name, strength & formulation of drug</td><td>Inactivated influenza vaccine suspension in a pre-filled syringe, including:
adjuvanted trivalent influenza vaccine (aTIV)
cell-based quadrivalent influenza vaccine (QIVc), Flucelvax® Tetra▼
egg-grown quadrivalent influenza vaccine (QIVe)
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 re-imbursement under the NHS influenza vaccination programme in 2020/21.

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.

Inactivated influenza vaccine selection<table><tr><th>Age</th><th>Recommended influenza vaccine for adults and children unable to receive LAIV</th></tr><tr><td>6 months to under 2 years</td><td>Offer a suitable QIVe.</td></tr><tr><td>2 years to 18 years</td><td>To children less than 9 years of age, offer a suitable QIVe.

To children aged 9 years and over who access the vaccine through general practice, QIVc should ideally be offered. Where QIVc vaccine is unavailable, GPs should offer QIVe.

It is acceptable to offer only QIVe to the small number of children unable to receive LAIV aged 9 years and over who are vaccinated in a school setting.

Note: The offer of an alternative inactivated influenza vaccine to those in routine age cohorts (not in clinical risk groups) who do not accept LAIV due to porcine gelatine should only be made once the additional DHSC procured stock (see Supplies section) is available.</td></tr><tr><td>18 years to under 65 years</td><td>Offer QIVc or QIVe (as an alternative to QIVc).</td></tr><tr><td>65 years and over[3]</td><td>Offer aTIV (see Off-label use section).

QIVc is suitable for use in this age group if aTIV is not available or is not suitable due to egg allergy.</td></tr></table></td></tr>
<tr><td>Legal category</td><td>Prescription only medicine (POM).</td></tr>
<tr><td>Black triangle▼

Continued over page</td><td>QIVc and QIVe products, with the exception of Fluarix® Tetra, are black triangle.</td></tr>
</table>

Black triangle▼ (continued)	This information was accurate at the time of writing. See product SPCs at www.medicines.org.uk for indication of current black triangle status.
Off-label use	The 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 2021 in accordance with the recommendations for the national influenza immunisation programme for 2020/21. 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. 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. 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 the table of Influenza Vaccines for the 2020 to 2021 season for more information.
Route / method of administration Continued over page	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. 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. 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. Influenza vaccines licensed for intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. Note: Fluarix® Tetra, Flucelvax® Tetra▼ and

Route / method of administration (continued)	aTIV are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD. 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. 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 needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs. Shake vaccine before administration. Inspect visually prior to administration and ensure appearance is consistent with the description in the products SPC. The SPCs provide further guidance on administration and are available from the electronic Medicines Compendium website: www.medicines.org.uk
Dose and frequency of administration	Single 0.5ml dose to be administered for the current annual flu season. 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). 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.
Duration of treatment	Single 0.5ml dose for the current annual flu season (1 September 2020 to 31 March 2021). 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.
Quantity to be supplied / administered	Single dose of 0.5ml per administration.
Supplies Continued over page	Centrally procured QIVe vaccine available via ImmForm should be used to vaccinate all children aged under 9 years in clinical risk groups if LAIV is unsuitable. QIVc for administration in a GP setting to children aged 9 to 17 years in clinical risk groups for whom LAIV is unsuitable should be locally procured from the influenza vaccine manufacturers/wholesalers and will be reimbursed by NHS E&I in 2020/21 in the same way as for all adult flu vaccines. Where QIVe is used for this group, this may be either locally procured by GP Practices or accessed via ImmForm. Where QIVe is administered in a school setting to children aged 9 years and over who are in a clinical risk group and unable to receive LAIV, centrally supplied QIVe should be used.

Supplies (continued)	This season, to support the expanded flu programme and expected increased demand for flu vaccine across all cohorts, the Department of Health and Social Care (DHSC) has procured additional national supply of inactivated influenza vaccines and will issue guidance in September on how this can be accessed. It will be subject to the availability of this supply, although not limited to it, that inactivated influenza vaccine may be offered to: individuals aged under 65 years, or as an alternative to LAIV for individuals in routine age cohorts (not in clinical risk groups) who do not accept porcine gelatine. This is not anticipated before November 2020. The date from when inactivated influenza vaccine may be administered to these individuals will be formally announced later in the flu season. A copy of this announcement will be made available at: https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).
Storage	Store at +2°C to +8°C. Do not freeze. Store in original packaging in order to protect from light. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and 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. Inactivated influenza vaccine may be given at the same time as other vaccines (See Route / method of administration). 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
Identification & management of adverse reactions Continued over page	Pain, swelling or redness at the injection site, low-grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms after intramuscular vaccination. A small painless nodule (induration) may also form at the injection site. These symptoms usually disappear within 1 to 2 days without treatment. Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur. A higher incidence of mild post-immunisation reactions has been reported with aTIV compared to non-adjuvanted influenza vaccines.

Identification & management of adverse reactions (continued)	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. 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
Reporting procedure of adverse reactions	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 QIVc and QIVe, with the exception of Fluarix® Tetra, are black triangle. Therefore, any suspected adverse reactions should be reported via the Yellow Card Scheme. 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 marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Patient advice / follow up treatment	Individuals should be advised regarding adverse reactions to vaccination and reassured that the inactivated vaccine cannot cause influenza. However, the vaccine will not provide protection for about 14 days and does not protect against other respiratory viruses that often circulate during the flu season. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Therefore, consideration should be given to the influenza vaccination of their household contacts. Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. When applicable, advise the individual/parent/carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations / additional information Continued over page	Further guidance on vaccination during the COVID-19 pandemic is available in Clinical guidance for healthcare professionals on maintaining immunisation programmes during COVID-19. Ensure there is 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. For children under the age of 16 years, those assessed as Gillick competent can self-consent (for further information on consent see Reference guide to consent for examination or treatment). For vaccination of those aged 9 to less than 65 years of age in a clinical at-risk group (including pregnant women), there is a potential

Special considerations / additional information (continued)	advantage to using cell-culture influenza vaccines (QIVc) compared with egg-culture vaccines (QIVe), due to the possible impact of 'egg-adaptation' on the effectiveness of influenza vaccines, particularly against A(H3N2) strains. The available evidence supports a slight preference for QIVc over QIVe, because any impact will likely be limited to seasons in which the influenza season is dominated by well-matched H3N2 strains. The NHS Shielded Patient List may be subject to revision. The household contacts of those on the NHS Shielded Patient List current at the time of immunisation are eligible. 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. The aim is to further extend the vaccine programme in November and December to include the 50 to 64-year-old age group, subject to vaccine supply. This extension is being phased to allow you to prioritise those in at risk groups first. Providers will be given notice in order to have services in place for any additional cohorts later in the season. As in previous years LAIV will be the vaccine offered to the routine age cohorts for the childhood flu vaccination programme as this is the most effective vaccine for this programme. However, for 2020/21, consideration is being made to offer an injectable vaccine to those children whose parents object to the porcine gelatine in LAIV, to provide additional resilience against flu in what could be a challenging year. If the parent of a child eligible for the routine childhood immunisation programme refuses LAIV (and they understand that it is the most effective product) and they request an alternative vaccine, this should be offered to them where possible. To ensure that those in clinical risk groups are offered the vaccine first, the offer of an alternative inactivated influenza vaccine to those in routine age cohorts (not in clinical risk groups) who do not accept LAIV due to porcine gelatine should only be made once the additional DHSC procured stock (see Supplies section) is available. This is not anticipated before November 2020. The date from when inactivated influenza vaccine may be administered to these individuals will be formally announced later in the flu season. A copy of this announcement will be made available at: https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan. The licensed ages for the 2020/21 season influenza vaccines are: • QIVe split virion inactivated vaccines are licensed from 6 months of age • QIVe surface antigen inactivated vaccines are licensed from 3 years of age • QIVc, Flucelvax® Tetra▼, is licensed from 9 years of age • aTIV 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	Record: • that valid informed consent was given; • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or password controlled immuniser's 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, systems should be in place to ensure a record of vaccination is returned to the individual's general practice to allow clinical follow up and to avoid duplicate vaccination. For pregnant women, also record immunisation in the hand held and electronic maternity record if available. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	Inactivated influenza vaccination • 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 18 August 2020. https://www.gov.uk/government/collections/annual-flu-programme • The national flu immunisation programme 2020 to 2021: supporting letter. Published 14 May 2020 and update published 5 August 2020. https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan • Coronavirus (Covid-19): Shielded patients list. NHS Digital. Updated 18 August 2020. https://digital.nhs.uk/coronavirus/shielded-patient-list • Directed Enhanced Service Specification, Seasonal influenza and pneumococcal polysaccharide vaccination programme 2020/21. https://www.england.nhs.uk/gp/investment/gp-contract/https://www.england.nhs.uk/publication/gp-contract-2019-20-nhs-england-enhanced-service-specifications/ • Influenza vaccines: 2020 to 2021 flu season. 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. 16 July 2020 https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/ • Summary of Product Characteristics www.medicines.org.uk • Clinical guidance for healthcare professionals on maintaining immunisation programmes during COVID-19. https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-general-practice/ • Flu immunisation training recommendations. Updated 5 August 2020. https://www.gov.uk/government/publications/flu-immunisation-training-recommendations • Flu Vaccinations: Supporting people with learning disabilities. Updated 25 September 2018. https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities **General** • 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

Continued over page

Key references (continued)	• 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 • Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them • PHE 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 • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • 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 and Social Care, published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

7. Practitioner authorisation sheet

Inactivated Influenza PGD v08.00 Valid from: 01/09/2020 Expiry: 31/03/2021

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

Practitioner

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

PGDs do not remove inherent professional obligations or accountability.

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

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

Authorising manager

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

Note to authorising manager

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

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

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/m²