Public Health England

PHE publications gateway number: 2015270

PATIENT GROUP DIRECTION (PGD)

Administration of intramuscular (or subcutaneous) inactivated influenza vaccine to individuals in accordance with the national immunisation programme for active immunisation against influenza.

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

Reference no:	IM Influenza PGD
Version no:	v06.00
Valid from:	01 September 2018
Review date:	01 April 2019
Expiry date:	31 March 2019

Public Health England has developed this PGD template 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.

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

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

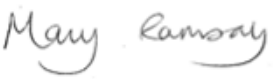
[1] This PGD is not relevant to the national community pharmacy seasonal influenza vaccination advanced service which has its own PGD (see Pharmacy Influenza Vaccination PGD).
[2] This includes any relevant amendments to legislation (eg 2013 No235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	18 August 2015
V02.00	PHE IM Influenza PGD amended to include health and social care workers with direct patient/service user contact, reflect the unavailability of egg-free influenza vaccine (Optaflu®) in 2016/17, reference the protocol for ordering storage and handling of vaccines and include PHE PGD template changes.	09 August 2016
V03.00	PHE IM Influenza PGD amended to remove text pertaining to non-payment for vaccinating morbidly obese individuals, exclude individuals who have received a dose of influenza vaccine for the current season, remove names of low ovalbumin vaccines and instead link to Influenza vaccine ovalbumin content document, refer generically to quadrivalent inactivated influenza vaccine, state that patients should be 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, add paragraph on patient consent to off-label section and include minor typographical and layout changes in keeping with PHE PGD Policy.	04 July 2017
V04.00	PHE IM Influenza PGD amended to remove requirement to use CHIS.	17 August 2017
V05.00	PHE IM Influenza PGD amended to include immunisation of 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 patients/clients who are at increased risk from exposure to influenza.	01 November 2017
V06.00	PHE IM Influenza PGD amended to: • include additional healthcare practitioners in Section 3 • include adjuvanted trivalent influenza vaccine Fluad® 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

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, PHE		10/08/2018
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		10/08/2018
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		10/08/2018

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
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 South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England 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 London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East
Sharon Webb	Programme Manager - IDPS , NHS Screening Programmes, Public Health England (Midwife)
Helen Wilkinson	Principal Pharmacist Bristol, North Somerset & South Gloucestershire Clinical Commissioning Group.

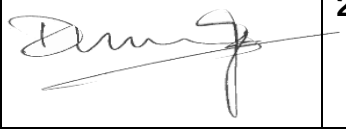
2. Organisational authorisations

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 MIDLANDS AND EAST (CENTRAL MIDLANDS authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
General medical practices from which NHS England Midlands and East (Central Midlands) commissions immunisation services
Limitations to authorisation

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Deputy Medical Director, NHS England Midlands and East (Central Midlands)	**Dr Dave Briggs**		**20th August 2018**

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

Local enquiries regarding the use of this PGD may be directed to:

For **Bedfordshire, Hertfordshire, Luton and Milton Keynes** - england.immsqa@nhs.net - the (Central Midlands) South public health/screening and immunisation team.

For **Leicestershire, Lincolnshire and Northamptonshire** – england.llimms@nhs.net - the (Central Midlands) North and Central public 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	Registered professional with one of the following bodies: • 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) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all 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 • 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 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", the annual flu letter and subsequent correspondence/publications from PHE and/or NHS England.

Criteria for inclusion
 	
Continued over page
	This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer influenza immunisation beyond the groups they are commissioned to immunise.
	
	In 2018/19, flu vaccinations should be offered to the following groups:
	• people aged 65 years or over (including those becoming age 65 years by 31 March 2019)
	• 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 three, four or five
	  ○ 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 (defined as BMI 40+)
	  ○ 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 vulnerable[3] patients/clients who are at increased risk from exposure to influenza

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

Criteria for inclusion (continued)	• 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 with direct patient/service user contact. Individuals not covered by the criteria above, should be vaccinated as part of an employer's occupational health obligation (see Chapter 12 of "The Green Book"). Note: This PGD may be used by NHS organisation's occupational health providers to vaccinate these individuals but does not extend to the immunisation of individuals other than those with direct patient/service user contact, as recommended for influenza vaccination by JCVI and detailed in Chapter 12.
Criteria for exclusion[5]	Individuals for whom no valid consent has been received (for further information on consent see DH Reference guide to consent for examination or treatment). Individuals who: • are less than 6 months of age • 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) • have had a severe anaphylactic reaction to egg which has previously required intensive care • are aged 2 years to under 18 years for whom live attenuated influenza vaccine (LAIV) is NOT contraindicated (or not otherwise unsuitable eg due to 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 received a dose of influenza vaccine for the current season, unless they are individuals aged 2 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 Continued over page	Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). With the exception of those individuals with a severe anaphylaxis to egg which has previously required intensive care (see Criteria for exclusion), individuals with less severe egg allergy can be immunised in any setting using an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to

[4] Vulnerable means those patients/clients in a clinical risk group for flu or who are aged 65 years and over
[5] Exclusion under this Patient Group Direction 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 barium sulphate, 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)	0.06 micrograms in a 0.5 ml dose), see Influenza vaccine ovalbumin content. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Action to be taken if the 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 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. 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, as a PSD may be indicated. In a GP practice setting, 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. In a GP practice setting, inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy.

5. Description of treatment

Name, strength & formulation of drug

Inactivated influenza vaccine suspension in a pre-filled syringe, ie:

- inactivated quadrivalent influenza vaccine (QIV)
- inactivated adjuvanted trivalent influenza vaccine (aTIV)
- inactivated trivalent influenza vaccine (TIV)

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.

Recommended vaccine choice

Age	Recommended influenza vaccine
6 months to less than 2 years	Offer a suitable inactivated (split virion) quadrivalent influenza vaccine (QIV) supplied centrally via ImmForm. Note: LAIV (Fluenz Tetra®▼), adjuvanted trivalent influenza vaccine (aTIV, Fluad®) and inactivated (surface antigen) QIV from Mylan are not licensed in this age group.
2 years to under 18 years of age	Offer LAIV (Fluenz Tetra®▼) supplied centrally via ImmForm. For children in clinical risk groups under 18 years of age for whom LAIV is contraindicated (or is otherwise unsuitable, eg due to religious acceptance of porcine gelatin content), offer a suitable inactivated (split virion) QIV supplied centrally via ImmForm. Note: The aTIV (Fluad®) and inactivated (surface antigen) QIV from Mylan are not licensed in this age group.
18 years to under 65 years	Offer QIV. Note: LAIV (Fluenz Tetra®▼) and aTIV (Fluad®) are not licensed in this age group.
65 years and over (including 64 year olds turning 65 years by 31 March 2019)	The aTIV (Fluad®) is recommended as the adjuvanted vaccine is more effective than non-adjuvanted vaccine in this population. The use of the aTIV (Fluad®) should be a priority for those aged 75 years and over, given that the non-adjuvanted vaccine has shown no significant effectiveness in this group over recent seasons. QIV should be offered as a second line option to aTIV if aTIV is unobtainable (see Additional Information) or otherwise unsuitable (eg due to egg allergy). Note: LAIV (Fluenz Tetra®▼) is not licensed in this age group.
Note: Non-adjuvanted trivalent influenza vaccine (TIV) is not one of the recommended vaccines for 2018/19 but may be administered where the recommended vaccine choices as detailed above are unobtainable (see Additional Information).	

Legal category	Prescription only medicine (POM).
Black triangle▼	QIVs are black triangle (including GSK's Fluarix® Tetra▼ and MASTA, Mylan (BGP Products) and Sanofi Pasteur supplied QIV).
Off-label use	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 2019 in accordance with the recommendations for the national influenza immunisation programme for 2018/19. 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 Appendix F of the annual flu letter) 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 one year old. Due to the presence of adjuvant (MF59C), Fluad® should be administered intramuscularly using a 25mm needle. 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) 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. Influenza vaccines licensed for intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. Note: Fluarix® Tetra▼ and Fluad® are not licensed for subcutaneous administration so should only be administered intramuscularly under this PGD. 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

Route / method of administration (continued)	gauge or finer calibre) 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. 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 Fluad® 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 nine years old who have not previously received any doses of influenza vaccine should be offered a second dose of vaccine at least four weeks later. The inactivated influenza vaccines are interchangeable, although the individual's age 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 six 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. Children aged 6 months to less than nine years old offered inactivated influenza vaccine who have not received influenza vaccine previously should be offered a second dose of the vaccine at least four weeks later.
Quantity to be supplied / administered	Single dose of 0.5ml per administration.
Supplies Continued over page	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. Supplies for administration to adults should be ordered from the influenza vaccine manufacturers/wholesalers as in previous years. For children under 18 years of age, where Fluenz Tetra®▼is medically contraindicated or otherwise unsuitable, an inactivated QIV will be supplied. These vaccines should be ordered as per the usual mechanisms for the routine childhood immunisation programme.

Supplies (continued)	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. 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	Pain, swelling or redness at the injection site, low grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms after intramuscular vaccination. A small painless nodule (induration) may also form at the injection site. These symptoms usually disappear within one to two 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. 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 Continued over page	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

Reporting procedure of adverse reactions (continued)	QIVs are black triangle (including GSK's Fluarix® Tetra▼ and MASTA, Mylan (BGP Products) and Sanofi Pasteur supplied QIV). 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 individual/parent/carer when a subsequent vaccine dose is due. When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations / additional information Continued over page	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 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 DH Reference guide to consent for examination or treatment). The recommended vaccine in those aged 65 years and over is aTIV. QIV should not be offered to those aged 65 years and over, other than in exceptional circumstances. In the event that aTIV is not available, and is highly unlikely to become available, QIV may be offered as a second line option. Before offering the second line option, however, individuals should be sign-posted to other providers to access the recommended vaccine, as appropriate. Non-adjuvanted trivalent influenza vaccine (TIV) is not one of the recommended vaccines for 2018/19. For those aged under 65 years, if QIV is not available, and is highly unlikely to become available, TIV may be offered as a second line option. For those aged 65 years and over, if neither QIV nor aTIV are available, and are highly unlikely to become available, TIV may be administered in exceptional circumstances. In both situations, individuals should be sign-posted to other providers to access the recommended vaccine, as appropriate.

Special considerations / additional information (continued)	If offering QIV to individuals not recommended to have it, or if offering non-adjuvanted TIV to any individual, when gaining consent for immunisation, practitioners should ensure they inform the individual the vaccine is not one nationally recommended for them. Healthcare practitioners should ensure they explain to the individual the possible lower efficacy of the vaccine being offered to them, why it is being offered instead of the recommended vaccine and why it may still offer protection against seasonal flu, or attenuate the progression of the infection should they get it. The discussion should be documented in the individuals' records. Due to the risk of febrile convulsions, the indication for TIV from Pfizer (Influenza Vaccine (split virion, inactivated)) is restricted to use in adults and children aged five years and older. The SPC for TIV from Pfizer indicates that a high rate of fever was reported in the age group aged five to under nine years. This vaccine will not be part of the central supply for use in children in the 2018/19 season, but may be available for purchase by the practice. If no suitable alternative vaccines are available, clinicians should ensure parents are aware of the risk and give advice on the management of vaccine-induced fever. Licensed ages: • Fluarix® Tetra▼ and inactivated (split virion) QIV is licensed from 6 months of age • Mylan (BGP Products) inactivated (surface antigen) QIV is licenced from 18 years of age • The aTIV (Fluad®) is licensed for indiviudals aged 65 years and over (see Off-label section) • Influvac®, Imuvac®, Agrippal®, and surface antigen inactivated influenza vaccine (Mylan, BGP Products) TIVs are licensed from 6 months of age • Pfizer vaccines inactivated influenza vaccine (split virion) TIV is licensed from 5 years of age • 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 immunisers record on e-records). All records should be clear, legible and contemporaneous.
Continued over page	As a wide variety of influenza vaccines are available on the UK

Records (continued)	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. 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 15 August 2018 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Collection: Annual Flu Programme https://www.gov.uk/government/collections/annual-flu-programme • The national flu immunisation programme 2018 to 2019: supporting letter. Published 26 March 2018. https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan • Influenza vaccine ovalbumin content. https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content • Summary of Product Characteristics www.medicines.org.uk **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 • 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. January 2014. https://www.nice.org.uk/guidance/mpg2/resources • 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 • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines • 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

7. Practitioner authorisation sheet

IM Influenza PGD v06.00 Valid from: 01/09/2018 Expiry: 31/03/2019

Before signing this PGD, check that the document has had the necessary authorisations in section two. 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 _____ **(insert name of practice)** 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 (eg 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 (eg 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