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## Flublok Quadrivalent Patient Group Direction (PGD)

This PGD is for the administration of Flublok Quadrivalent (recombinant quadrivalent influenza vaccine, QIVr) to individuals in accordance with the national influenza immunisation programme.

This PGD is for the administration of Flublok Quadrivalent vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.<sup>1</sup>

Reference no: Flublok Quadrivalent PGD  
Version no: v01.00  
Valid from: 23 November 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)<sup>2</sup>. **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 as it relates to adults only. Provider organisations adopting authorised versions of this PGD should also retain copies for 8 years.

**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](mailto:immunisation@phe.gov.uk)

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: [jon.hayhurst@nhs.net](mailto:jon.hayhurst@nhs.net).

<sup>1</sup> 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).


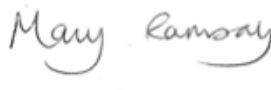

<sup>2</sup> This includes any relevant amendments to legislation (such as [2013 No.235](#), [2015 No.178](#), [2015 No.323](#) and [2020 No.1125](#)).

## Change history

Version number	Change details	Date
V01.00	New PHE PGD template for Flublok product, based on PHE IM Influenza PGD v08.00.	19 November 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
<b>Pharmacist</b> (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, Immunisation and Countermeasures, PHE		19/11/2020
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		19/11/2020
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		19/11/2020

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 Governance 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
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)
Vanessa Saliba	Consultant Medical Epidemiologist, Immunisation and Countermeasures, Public Health England
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 & NHS Improvement (South West)** authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England & NHS Improvement commissioned immunisation services within <ul style="list-style-type: none"> <li>• Bath &amp; North East Somerset, Swindon, and Wiltshire</li> <li>• Bristol, North Somerset, and South Gloucestershire</li> <li>• Cornwall and the Isles of Scilly</li> <li>• Devon</li> <li>• Dorset</li> <li>• Gloucestershire</li> <li>• Somerset</li> </ul>
Limitations to authorisation
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England and NHS Improvement (South West) must be used. This may include pharmacists working for primary care providers, however note that 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).
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 immunisation beyond the groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director, System Improvement and Professional Standards NHS England and NHS Improvement (South West)	Dr Caroline Gamlin MRCGP FFPH	<i>Caroline Gamlin</i>	24 November 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.swscreeningandimms@nhs.net](mailto:england.swscreeningandimms@nhs.net).

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

### 3. Characteristics of staff

<p><b>Qualifications and professional registration</b></p>	<p>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 <a href="#">Patient Group Directions: who can administer them</a>):</p> <ul style="list-style-type: none"> <li>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• 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)</li> <li>• 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)</li> <li>• dental hygienists and dental therapists registered with the General Dental Council</li> <li>• optometrists registered with the General Optical Council.</li> </ul> <p>Practitioners must also fulfil all the <a href="#">Additional requirements</a>.</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.</p>
<p><b>Additional requirements</b></p>	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>• must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using PGDs)</li> <li>• must be familiar with the vaccine product and alert to changes in the US prescribing information (package insert) and UK Patient Information Leaflet (PIL) provided with the product</li> <li>• must be alert to changes in Immunisation Against Infectious Disease (the '<a href="#">Green Book</a>'), and relevant national and local immunisation programmes</li> <li>• must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation</a>. For further information on immunisation training during the COVID-19 pandemic see <a href="#">Guidance on immunisation training during the COVID-19 pandemic</a> and <a href="#">Flu immunisation training recommendations</a></li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>• must be competent in the handling and storage of vaccines, and management of the cold chain</li> <li>• must be competent in the recognition and management of anaphylaxis</li> <li>• must have access to the PGD and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul>

	<b>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</b>
<b>Continued training requirements</b>	<p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and 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.</p>

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

<b>Clinical condition or situation to which this PGD applies</b>	<p>Flublok Quadrivalent is indicated under this PGD for the active immunisation of individuals for the prevention of influenza infection, in accordance with the national immunisation programme and recommendations given in <a href="#">Chapter 19</a> of the Immunisation Against Infectious Disease: the 'Green Book', <a href="#">annual flu letters</a> and subsequent correspondence/publications from PHE and/or NHS England and NHS Improvement.</p> <p>Note: This PGD covers NHS commissioned services. This PGD does not cover the provision of occupational health schemes or peer-to-peer influenza immunisation (See NHS Specialist Pharmacy Service '<a href="#">Written instruction</a>' template for the administration of inactivated seasonal influenza vaccine as part of an occupational health scheme, which may include peer-to-peer immunisation').</p>
<b>Criteria for inclusion</b>	<p>In 2020/21, influenza vaccine should be offered to the following groups:</p> <ul style="list-style-type: none"> <li>• people aged 50 years or over<sup>3</sup></li> <li>• people aged from 18 years to less than 65 years of age in a clinical risk group (see <a href="#">Appendix A</a>) such as: <ul style="list-style-type: none"> <li>○ chronic (long-term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis</li> <li>○ chronic heart disease, such as heart failure</li> <li>○ chronic kidney disease at stage 3, 4 or 5</li> <li>○ chronic liver disease</li> <li>○ chronic neurological disease, such as Parkinson's disease or motor neurone disease</li> <li>○ learning disability</li> <li>○ diabetes</li> <li>○ asplenia or splenic dysfunction</li> <li>○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)</li> <li>○ morbidly obese adults (aged from 16 years) with a BMI &gt; 40kg/m<sup>2</sup></li> <li>○ all pregnant women (including those women who become pregnant during the flu season)</li> </ul> </li> <li>• people living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of</li> </ul>
Continued over page	

<sup>3</sup> including those becoming age 50 years by 31 March 2021

<p><b>Criteria for inclusion</b> (continued)</p>	<p>infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions or university halls of residence</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• household contacts of those on the NHS <a href="#">Shielded Patient List</a>, 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</li> <li>• 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<sup>4</sup> patients/clients who are at increased risk from exposure to influenza</li> <li>• health and care staff, employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable<sup>4</sup> patients/clients who are at increased risk from exposure to influenza</li> <li>• 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.</li> </ul>
<p><b>Criteria for exclusion<sup>5</sup></b></p>	<p>Individuals for whom no valid consent has been received (for further information on consent see <a href="#">Reference guide to consent for examination or treatment</a>).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are less than 18 years of age</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of the vaccine</li> <li>• have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process<sup>6</sup></li> <li>• have received a complete dose of the recommended influenza vaccine for the current season</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> </ul>
<p><b>Cautions including any relevant action to be taken</b></p> <p>Continued over page</p>	<p>Individuals with a bleeding disorder may develop a haematoma at the injection site (see <a href="#">Route of Administration</a>).</p> <p>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.</p>

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

<sup>5</sup> 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

<sup>6</sup> Components include sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20; and residues from the manufacturing process may include baculovirus and Spodoptera frugiperda cell proteins (≤ 19 micrograms), baculovirus and cellular DNA (≤10 nanograms) and Triton X-100 (≤ 100 micrograms). Flublok Quadrivalent contains no egg proteins, antibiotics or preservatives and single dose pre-filled syringes contain no natural rubber latex.



<p><b>Cautions including any relevant action to be taken</b> (continued)</p>	<p>The package insert for Flublok Quadrivalent includes a precaution stating that ‘If Guillain-Barre syndrome [GBS] has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give Flublok Quadrivalent should be based on careful consideration of potential benefits and risks.’ The Green Book <a href="#">Chapter 19</a> highlights that GBS has been reported very rarely after influenza immunisation, with one case per million reported in one US study and no association found in other studies. However, a study found a strong association between GBS and influenza-like illness. This increased risk of GBS after influenza-like illness, if specific to infection with influenza virus, together with the absence of a casual association with influenza vaccine suggests that influenza vaccine should protect against GBS.</p>
<p><b>Action to be taken if the patient is excluded</b></p>	<p>The risk to the individual of not being immunised must be taken into account. The indications for flu vaccination are not exhaustive, and the healthcare practitioner should consider the risk of flu exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from flu itself. Where appropriate, such individuals should be referred, or a PSD obtained for immunisation.</p> <p>In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged.</p> <p>Document the reason for exclusion and any action taken in the individual’s clinical records.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual’s clinician as required.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p>
<p><b>Action to be taken if the patient or carer declines treatment</b></p>	<p>Informed consent, from the individual or a person legally able to act on the person’s behalf, must be obtained.</p> <p>Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>As per local policy.</p>



## 5. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	<p>Flublok Quadrivalent (recombinant quadrivalent influenza vaccine, QIVr) in a 0.5ml single dose pre-filled syringe.</p> <p>For the administration of other 2020/21 seasonal inactivated influenza vaccines, please refer to PHE Inactivated Influenza PGD v08.00.</p> <p>A <a href="#">list of the influenza vaccines</a> available in the UK was published in the <a href="#">annual flu letter</a> for England and subsequent updates can be found in <a href="#">Vaccine Update</a>.</p>
<b>Legal category</b>	<p>Flublok Quadrivalent does not have a UK marketing authorisation. It has been provided temporary authorisation by the Medicines &amp; Healthcare products Regulatory Agency (MHRA) for supply in the UK under regulation 174 and 174A of HMR2012 as announced at: <a href="https://www.gov.uk/government/news/flublok-vaccine-given-authorisation-for-temporary-supply-in-the-uk-to-meet-public-health-need">https://www.gov.uk/government/news/flublok-vaccine-given-authorisation-for-temporary-supply-in-the-uk-to-meet-public-health-need</a></p> <p>In accordance with the <a href="#">UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020</a>, a PGD may now be used to supply and/or administer a medicine authorised under regulation 174. The regulation 174 authorised product is categorised as a prescription only medicine (POM).</p>
<b>Black triangle ▼</b>	<p>Flublok Quadrivalent does not have a UK marketing authorisation and is authorised for temporary supply in the UK in accordance with a Regulation 174 authorisation. The product has been used in the US for several years, so it is not necessarily the case that, were it to be licensed in the UK, it would have black triangle status. However, as a vaccine product, MHRA have a specific interest in the reporting of adverse drug reactions for this product, see <a href="https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/">https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/</a></p>
<b>Off-label use</b>	<p>This product is supplied in the UK in accordance with regulation 174 and does not have a UK marketing authorisation.</p> <p>As part of the consent process, inform the individual/carer that this vaccine does not have a UK marketing authorisation but has been authorised for temporary supply in the UK by the MHRA and has been licensed and used in the US since 2013 and that it is being offered in accordance with national guidance.</p>
<b>Route / method of administration</b>	<p>Flublok Quadrivalent is for administration by intramuscular injection, preferably into deltoid region of the upper arm.</p> <p>Invert the pre-filled syringe containing Flublok Quadrivalent gently prior to affixing the appropriate size needle for intramuscular administration.</p> <p>Flublok Quadrivalent is supplied from the manufacturer without a needle. The syringe has a luer-lock adapter, these luer-lock syringes can accommodate either a luer-lock or luer-slip needle. The needle needs to be sufficiently long to ensure that the vaccine is injected into the muscle. For most adults a 25mm 23G (blue) or 25mm 25G</p>

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<p><b>Route / method of administration</b> (continued)</p>	<p>(orange) needle should be used. In larger adults, a longer length (38mm) needle may be required.</p> <p>Flublok Quadrivalent is a clear, colourless solution. Inspect visually for particulate matter and discolouration prior to administration. If either exists, the vaccine should not be administered.</p> <p>Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23G or finer calibre such as 25G) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy.</p> <p>Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (equal to 23G or finer calibre such as 25G) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.</p> <p>When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations.</p> <p>The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.</p>
<p><b>Dose and frequency of administration</b></p>	<p>Single 0.5ml dose to be administered for the current annual flu season.</p>
<p><b>Duration of treatment</b></p>	<p>Single 0.5ml dose for the current annual flu season (up to 31 March 2021).</p>
<p><b>Quantity to be supplied / administered</b></p>	<p>Single dose of 0.5ml.</p>
<p><b>Supplies</b></p>	<p>This season, to support the expanded flu programme and expected increased demand for flu vaccine, the Department of Health and Social Care (DHSC) has procured additional national supply of inactivated influenza vaccines, including Flublok Quadrivalent, and will update the <a href="#">guidance for GPs</a> and <a href="#">guidance for NHS providers</a> on how this can be accessed.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book <a href="#">Chapter 3</a>).</p>

<b>Storage</b>	<p>Store at +2°C to +8°C. Do not freeze. Store in original packaging in order to protect from light.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued unlicensed use or appropriate disposal. Refer to <a href="#">PHE Vaccine Incident Guidance</a>.</p>
<b>Disposal</b>	<p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the <a href="#">technical memorandum 07-01</a>: Safe management of healthcare waste (Department of Health, 2013).</p>
<b>Drug interactions</b>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.</p> <p>Data evaluating the concomitant administration of Flublok Quadrivalent with other vaccines are not available. In accordance with general principles for inactivated vaccines, inactivated influenza vaccine may be given at the same time as other vaccines (See <a href="#">Route / method of administration</a>).</p>
<b>Identification &amp; management of adverse reactions</b>	<p>Injection-site reactions of tenderness and pain and systemic reactions of headache, fatigue, myalgia and arthralgia are among the commonly reported symptoms after intramuscular vaccination.</p> <p>Immediate reactions to vaccination such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur.</p> <p>The frequency of injection site pain and systemic reactions may be higher in individuals vaccinated concomitantly with inactivated influenza vaccine and pneumococcal polysaccharide vaccine (PPV23) compared to vaccination with influenza vaccine alone and similar to that observed with PPV23 vaccination alone. Influenza vaccine and PPV23 may be administered at the same visit.</p> <p>A detailed list of adverse reactions is available in the US prescribing information (package insert), which is provided with the product.</p>
<b>Reporting procedure of adverse reactions</b>	<p>Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></p> <p>As a vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product, see <a href="https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/">https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/</a></p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p>
<b>Written information to be given to patient or carer</b>	<p>Provide the <a href="#">UK patient information leaflet (PIL)</a> for Flublok Quadrivalent.</p>
<b>Patient advice / follow up treatment</b>	<p>Individuals should be advised regarding adverse reactions to vaccination and reassured that the vaccine contains non-infectious</p>

<p><b>Patient advice / follow up treatment</b> (continued)</p>	<p>proteins that cannot cause influenza. However, the vaccine will not provide protection for about 14 days and does not protect against other respiratory viruses that often circulate during the flu season.</p> <p>Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Therefore, consideration should be given to the influenza vaccination of their household contacts.</p> <p>Inform the individual/carer of possible side effects and their management.</p> <p>The individual/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>Advise the individual/carer that annual vaccination to prevent influenza is recommended where they remain eligible for the national influenza immunisation programme.</p>
<p><b>Special considerations / additional information</b></p>	<p>Further guidance on vaccination during the COVID-19 pandemic is available in <a href="#">Clinical guidance for healthcare professionals on maintaining immunisation programmes during COVID-19</a>.</p> <p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination.</p> <p>Flublok Quadrivalent (Influenza Vaccine) is a recombinant quadrivalent influenza vaccine (QIVr) which contains purified recombinant haemagglutinin proteins, of the four strains of the influenza virus specified by the health authorities for inclusion in the annual seasonal influenza vaccine, produced in a continuous insect cell line.</p> <p>This vaccine (Flublok) has been used in the US since 2013 and is licensed in the US for use in those aged 18 years and above. The potential use of QIVr in the UK was discussed by JCVI in June 2020. QIVr was shown to provide superior protection to egg-based vaccine in older adults in a US trial over the 2014-15 season. JCVI have therefore advised that QIVr, QIVc, aTIV and HD TIV are suitable for use in those aged 65 years and over and are preferable to standard egg based inactivated trivalent and quadrivalent vaccines (TIVe and QIVe). JCVI have also advised that QIVr, QIVc and QIVe are suitable vaccines for use in those less than 65 years of age and in an at-risk group.</p> <p>Flublok Quadrivalent contains no egg proteins, antibiotics or preservatives and single dose pre-filled syringes contain no natural rubber latex.</p> <p>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.</p> <p>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.</p> <p>Individuals with learning disabilities may require reasonable adjustments to support vaccination (see <a href="https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities">https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities</a>). A PSD may be required.</p>

<p><b>Records</b></p>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given;</li> <li>• name of individual, address, date of birth and GP with whom the individual is registered</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via PGD</li> </ul> <p>Records should be signed and dated (or password-controlled immuniser's record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>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.</p> <p>For pregnant women, also record immunisation in the hand held and electronic maternity record if available.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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## 6. Key references

<p>Key references</p> <p>Continued over page</p>	<p><b>Flublok Quadrivalent Vaccine</b></p> <ul style="list-style-type: none"><li>• Immunisation Against Infectious Disease: The Green Book, <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">Chapter 19</a>. Published 29 October 2020. <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li><li>• Collection: Annual Flu Programme. Updated 06 October 2020. <a href="https://www.gov.uk/government/collections/annual-flu-programme">https://www.gov.uk/government/collections/annual-flu-programme</a></li><li>• The national flu immunisation programme 2020 to 2021: supporting letter. Published 14 May 2020 and update published 5 August 2020. <a href="https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan">https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan</a></li><li>• Coronavirus (Covid-19): Shielded patients list. NHS Digital. Updated 18 August 2020. <a href="https://digital.nhs.uk/coronavirus/shielded-patient-list">https://digital.nhs.uk/coronavirus/shielded-patient-list</a></li><li>• Directed Enhanced Service Specification, Seasonal influenza and pneumococcal polysaccharide vaccination programme 2020/21. <a href="https://www.england.nhs.uk/gp/investment/gp-contract/">https://www.england.nhs.uk/gp/investment/gp-contract/</a></li><li>• Influenza vaccines: 2020 to 2021 flu season. <a href="https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content">https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content</a></li><li>• Accessing government-secured flu vaccines: guidance for NHS providers. Published 2 November 2020. <a href="https://www.gov.uk/government/publications/accessing-government-secured-flu-vaccines-guidance-for-nhs-providers">https://www.gov.uk/government/publications/accessing-government-secured-flu-vaccines-guidance-for-nhs-providers</a></li><li>• Accessing government-secured flu vaccines: guidance for GPs. Published 9 October 2020. <a href="https://www.gov.uk/government/publications/accessing-government-secured-flu-vaccines-guidance-for-gps">https://www.gov.uk/government/publications/accessing-government-secured-flu-vaccines-guidance-for-gps</a></li><li>• Written instruction for the administration of seasonal 'flu vaccination. NHS Specialist Pharmacy Service. 22 October 2020 <a href="https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/">https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/</a></li><li>• Flublok vaccine given authorisation for temporary supply in the UK to meet public health need <a href="https://www.gov.uk/government/news/flublok-vaccine-given-authorisation-for-temporary-supply-in-the-uk-to-meet-public-health-need">https://www.gov.uk/government/news/flublok-vaccine-given-authorisation-for-temporary-supply-in-the-uk-to-meet-public-health-need</a></li><li>• UK Patient information leaflet (PIL) for Flublok Quadrivalent <a href="https://products.mhra.gov.uk/search/?search=flublok&amp;page=1">https://products.mhra.gov.uk/search/?search=flublok&amp;page=1</a></li><li>• Clinical guidance for healthcare professionals on maintaining immunisation programmes during COVID-19. <a href="https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-general-practice/">https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-general-practice/</a></li><li>• Flu immunisation training recommendations. Updated 5 August 2020. <a href="https://www.gov.uk/government/publications/flu-immunisation-training-recommendations">https://www.gov.uk/government/publications/flu-immunisation-training-recommendations</a></li><li>• Flu Vaccinations: Supporting people with learning disabilities. Updated 25 September 2018.</li></ul>
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<p><b>Key references</b> (continued)</p>	<p><a href="https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities">https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities</a></p> <p><b>General</b></p> <ul style="list-style-type: none"> <li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <a href="https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste">https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste</a></li> <li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 <a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li> <li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. <a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li> <li>• Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. <a href="https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them">https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them</a></li> <li>• PHE Guidance on immunisation training during the COVID-19 pandemic. 26 June 2020. <a href="https://www.gov.uk/government/publications/immunisation-training-guidance-during-the-covid-19-pandemic/guidance-on-immunisation-training-during-the-covid-19-pandemic">https://www.gov.uk/government/publications/immunisation-training-guidance-during-the-covid-19-pandemic/guidance-on-immunisation-training-during-the-covid-19-pandemic</a></li> <li>• PHE Immunisation Collection <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li> <li>• PHE Vaccine Incident Guidance <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li> <li>• Reference guide to consent for examination or treatment, Department of Health and Social Care, published 4 August 2009. <a href="https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition">https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition</a></li> <li>• UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 <a href="https://www.legislation.gov.uk/ukSI/2020/1125/contents/made">https://www.legislation.gov.uk/ukSI/2020/1125/contents/made</a></li> </ul>
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## 7. Practitioner authorisation sheet

**Flublok Quadrivalent PGD v01.00 Valid from: 23/11/2020 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 <b>insert name of organisation</b> 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)
<b>Chronic respiratory disease</b>	<p>Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission.</p> <p>Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD).</p> <p>Children who have previously been admitted to hospital for lower respiratory tract disease.</p>
<b>Chronic heart disease</b>	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
<b>Chronic kidney disease</b>	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
<b>Chronic liver disease</b>	Cirrhosis, biliary atresia, chronic hepatitis.
<b>Chronic neurological disease (included in the DES directions for Wales)</b>	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.
<b>Diabetes</b>	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes.
<b>Immunosuppression (see <i>contraindications and precautions section on live attenuated influenza vaccine</i>)</b>	<p>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).</p> <p>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.</p> <p>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.</p> <p>Some immunocompromised patients may have a suboptimal immunological response to the vaccine.</p>
<b>Asplenia or dysfunction of the spleen</b>	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
<b>Pregnant women</b>	Pregnant women at any stage of pregnancy (first, second or third trimesters).
<b>Morbid obesity (class III obesity)</b>	Adults with a Body Mass Index $\geq 40$ kg/m <sup>2</sup>