AGREEMENT FOR VACCINATION SERVICES OF DISTRICT OR COMMUNITY NURSES [TO BE TYPED ON HEADED NOTEPAPER OF THE PRACTICE AND THE TEXT IN THESE SQUARE BRACKETS DELETED]

PARTIES

(1) [FULL GP NAME AND ADDRESS](“**Practice**”)

(2) [FULL TRUST / FOUNDATION TRUST NAME AND ADDRESS](“**Employer**”)

Each a (“party”) and together the (“parties”) to this agreement.

BACKGROUND

The parties wish to make arrangements for District and/or Community Nurses ("**DN/CN**") employed by the Employer to administer seasonal influenza vaccinations on behalf of the Practice, in accordance with the terms set out below.

AGREED TERMS

1. Agreement to administer vaccinations

1.1 The parties hereby agree that the Employer shall agree their employed DN/CNs shall perform the Services on behalf of the Practice on the terms of this Agreement and as set out in Schedules 1 and 2**.**

1.2 The parties acknowledge and agree that this Agreement does not give rise to an employment relationship between the DN/CN and the Practice or to any other relationship between the parties other than on the terms set out in this letter. For the avoidance of doubt, neither the DN/CN nor the Employer will be entitled to any form of payment from the Practice either during the Agreement (including expenses, sick pay or holiday pay) or upon its cessation.

1.3 The Employer acknowledges and agrees that it will at all times remain the substantive employer of the DN/CN. This Agreement will not affect the terms and conditions of the contracts of employment the Employer already holds with the DN/CN. The Employer will immediately notify the Practice in writing should any of its contracts of employment with the DN/CN come to an end during the period of this Agreement.

2. Employer's obligations

2.1 **General.** The Employer shall ensure that at all times during the term of this Agreement the DN/CN shall :

(a) act towards the Practice conscientiously and in good faith and not allow his or her personal interests to conflict with the duties he or she owes to the Practice under this Agreement and the general law.

(b) Except as authorised by the Practice in this Agreement or otherwise in writing, not act in a way which will incur any liabilities on behalf of the Practice.

(c) comply with the policies of the Employer and applicable professional standards.

(d) shall comply with all reasonable and lawful instructions of the Practice from time to time concerning the Services.

(e) keep the Practice fully informed of its activities concerning the Services and shall provide the Practice with reports on request. The DN/CN shall notify the Practice as soon as is practicable after each vaccination has been completed for each patient and shall update the Patient record within 24 hours.

(f) maintain appropriate, up-to-date and accurate records relating to the manner in which the Services were supplied.

2.2 **Disputes.** The Employer shall not without prior reference to the Practice (and then only acting strictly on the Practice's express instructions) take part in any dispute or commence or defend any court or other dispute proceedings on behalf of the Practice or settle or attempt to settle or make any admission concerning any such proceedings.

3. Compliance with laws

3.1 Each party shall at its own expense comply with all laws and regulations relating to its activities under this Agreement, as they may change from time to time, and with any conditions binding on it in any applicable licences, registrations, permits and approvals.

4. Data protection

4.1 **Definitions.**

Agreed Purposes: The administration of vaccinations to patients during the flu season 2018/19 and the updating of those patients records, as further detailed in Schedules 1 and 2.

Data subject, personal data, processing: as set out in the Data Protection Legislation in force at the time.

Data Protection Legislation: all legislation and regulatory requirements in force from time to time relating to the use of personal data and the privacy of electronic communications, including, without limitation (i) any data protection legislation from time to time in force in the UK including the Data Protection Act 2018 or any successor legislation, as well as (ii) the General Data Protection Regulation (*(EU) 2016/679*) and any other directly applicable European Union regulation relating to data protection and privacy (for so long as and to the extent that the law of the European Union has legal effect in the UK).

4.2 **Data sharing.** Each party shall:

(a) process personal data only to the extent required for the Agreed Purposes;
(b) comply with the Data Protection Legislation when processing personal data; and
(c) assist the other in complying with the Data Protection Legislation, as reasonably requested.

5. Professional liability and insurance

5.1 The Practice acknowledges and agrees that any action or inaction taken in the course of provision of the Services by the DN/CN on behalf of the Practice and in compliance with this Agreement shall be covered by the Practice's indemnity cover.

6. Duration and termination

6.1 This Agreement shall commence on the 1 September 2018 and shall continue in force until the 31 March 2019 or until it is terminated by either party giving 1 month's notice, in writing, to the other party.

6.2 Termination of this Agreement shall not affect any rights, remedies, obligations or liabilities of the parties that have accrued up to the date of termination, including the right to claim damages for any breach of the Agreement which existed at or before the date of termination.

7. Assignment and other dealings.

(a) The Employer shall not assign, transfer, charge, subcontract, declare a trust over or deal in any other manner with any or all of its rights and obligations under this Agreement without the Practice's prior written consent.

(b) The Practice may at any time assign, transfer, charge, subcontract, declare a trust over or deal in any other manner with any or all of its rights under this Agreement.

Signature …….. **Date…….**

[NAME]

On behalf of **[INSERT NAME OF PRACTICE]**

Signature …….. **Date…….**

On behalf of **[INSERT NAME OF TRUST]**

Schedule 1

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.

[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*).

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:

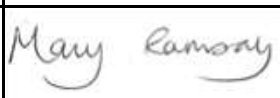
immunisation@phe.gov.uk

Chapter 2 **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.

INSERT AUTHORISING BODY NAME authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
eg All NHS England commissioned immunisation services or NHS Trusts providing immunisation services.
Limitations to authorisation
eg Any local limitations the authorising organisation feels they need to apply in line with the way services are commissioned locally. This organisation does not authorise the use of this PGD by …

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Complete eg NHS England Governance Lead, Medical Director			

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

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

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	**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

Continued over page **Criteria for inclusion** (continued)	• 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 • 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

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

	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 **Cautions including any relevant action to be taken** (continued)	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 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

<table>
<tr>
<td>Name, strength & formulation of drug</td>
<td>
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
<table>
<tr><th>Age</th><th>Recommended influenza vaccine</th></tr>
<tr><td>6 months to less than 2 years</td><td>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.</td></tr>
<tr><td>2 years to under 18 years of age</td><td>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.</td></tr>
<tr><td>18 years to under 65 years</td><td>Offer QIV.

Note: LAIV (Fluenz Tetra®▼) and aTIV (Fluad®) are not licensed in this age group.</td></tr>
<tr><td>65 years and over (including 64 year olds turning 65 years by 31 March 2019)</td><td>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</td></tr>
</table>
</td>
</tr>
</table>

	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	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

Continued over page **Route / method of administration** (continued)	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 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 **Supplies** (continued)	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. 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 **Reporting procedure of adverse reactions** (continued)	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* 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	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. 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.
Continued over page **Special considerations / additional information** (continued)	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 Continued over page **Records** (continued)	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. As a wide variety of influenza vaccines are available on the UK market each year, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records. It is important that vaccinations given either at a general practice or elsewhere (for example at antenatal clinics) are recorded on appropriate health records for the individual (using the appropriate clinical code) in a timely manner. If given elsewhere, a record of vaccination should be returned to the individual's general practice to allow clinical follow up and to avoid duplicate vaccination. 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* • he 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 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 (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

Schedule 2

PATIENT GROUP DIRECTION (PGD)

Administration of 23-valent pneumococcal polysaccharide vaccine (PPV)to individuals from 65 years of age and individuals from 2 years of age in a clinical risk group in accordance with the national immunisation programme for active immunisation against pneumococcal disease and UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings.

PHE publications gateway number: 2016262

This PGD is for the administration of 23-valent pneumococcal polysaccharide vaccine (PPV) by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no: PPV PGD

Version no: v02.00

Valid from: 1 September 2018

Review date: 1 March 2020

Expiry date: 31 August 2020

Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisation in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[7]. **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.

[7] This includes any relevant amendments to legislation (eg *2013 No.235*, *2015 No.178* and *2015 No.323*).

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 PGDs 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:

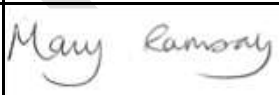
immunisation@phe.gov.uk

Chapter 3 **Change history**

Version number	Change details	Date
V01.00	New PHE PGD template	01 September 2016
V02.00	PPV PGD amended to: • include vaccination in accordance with UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings • include 64 year olds who may be immunised during the influenza season and who will turn 65 years by the 31 March • include both vial and pre-filled syringe presentations of PPV • include additional healthcare practitioners in Section 3 • refer to PHE vaccine incident guidance within the off-label and storage sections • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	08 August 2018

- **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		09/08/2018
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		08/08/2018
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		09/08/2018

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 / Public Health 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/Registered Midwife, NBHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Deputy Head of Medicines Management, NHS South Gloucestershire Clinical Commissioning Group

- **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.

INSERT AUTHORISING BODY NAME authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
eg All NHS England commissioned immunisation services or NHS Trust providing immunisation services.
Limitations to authorisation
eg Any local limitations the authorising organisation feels they need to apply in-line with the way services are commissioned locally. This organisation does not authorise the use of this PGD by ….

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Complete eg NHS England Governance Lead, Medical Director			

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

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

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.

- ***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 privately provided community pharmacy services) • paramedics and physiotherapists 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 Training* • 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.

- **Clinical condition or situation to which this PGD applies**

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals from 65 years of age and individuals from 2 years of age in a clinical risk group, for the prevention of pneumococcal disease in accordance with the national immunisation programme, *UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings* and recommendations given in *Chapter 25* of Immunisation Against Infectious Disease: "The Green Book".
Criteria for inclusion	Individuals who: • are aged 65 years and over (including those 64 year olds who may be immunised during the influenza season and who will turn 65 years by the 31 March)[8] • are aged 2 years and over and have a medical condition included in the clinical risk groups defined in the Green Book *Chapter 25* Table 25.1 (copy provided at *Appendix A*) • have asplenia, splenic dysfunction or chronic kidney disease (see *Appendix A*) and require a pneumococcal polysaccharide vaccine (PPV) booster • are a close contact recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with *UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings*
Criteria for exclusion[9]	Individuals for whom no valid consent has been received. Individuals who: • are less than 2 years of age • have previously received PPV over the age of 2 years, except individuals with asplenia, splenic dysfunction and chronic kidney disease (see *Appendix A*) and those recommended vaccination for the public health management of clusters of serious pneumococcal disease in closed settings

[8] The NHS England Directed Enhanced Service (DES) for pneumococcal polysaccharide vaccination (PPV23) is renewed annually. Historically the DES allows PPV23 to be administered to those aged 64 years if they attain 65 years of age by the 31st March. This is to facilitate co-administration of both PPV23 and influenza vaccine at the same practice visit.

[9] 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

	• have had a confirmed anaphylactic reaction to a previous dose of PPV or to any component of the vaccine • have asplenia, splenic dysfunction or chronic kidney disease (see *Appendix A*) and received PPV in the preceding 5 years • have received pneumococcal conjugate vaccine (PCV) in the preceding 2 months • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • are at risk of frequent or continuous occupational exposure to metal fume (eg welders) (indication not covered by this PGD)

Continued over page

Cautions including any relevant action to be taken	Antibody response may be impaired in those with immunological impairment and those with an absent or dysfunctional spleen (see *Special considerations / additional information* section regarding appropriate timing of vaccination).
Action to be taken if the patient is excluded	If aged less than 2 years PPV is not indicated, ensure PCV immunisation is up-to-date. If aged from 2 years to less than 65 years and neither in a clinical risk group nor recommended vaccination for the public health management of clusters of serious pneumococcal disease in closed settings, PPV is not indicated. If PPV has previously been received over the age of 2 years and the individual does not have asplenia, splenic dysfunction or chronic kidney disease (see *Appendix A*) and the individual is not recommended vaccination for the public health management of clusters of serious pneumococcal disease in closed settings, further PPV is not indicated. Individuals with asplenia, splenic dysfunction or chronic kidney disease (see *Appendix A*), who have received PPV within the preceding 5 years, defer immunisation until appropriate interval. Individuals who have received PCV in the preceding 2 months postpone immunisation until 2 months has elapsed. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is

	arranged. Individuals who are at risk of frequent or continuous occupational exposure to metal fume (eg welders) should be considered for immunisation taking into account exposure control measures in place. This is outside the remit of this PGD. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. 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. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. 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

- **Description of treatment**

Name, strength & formulation of drug	23-valent pneumococcal polysaccharide vaccine (PPV) eg: • Pneumococcal polysaccharide vaccine[10], 0.5ml solution for injection in a vial or pre-filled syringe, with each 0.5ml dose containing 25 micrograms of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Concomitant administration of PPV and shingles vaccine (Zostavax®) is off-label but may occur when indicated in accordance with the advice in *Chapter 28a* of "The Green Book", see *Drug Interactions* below. Administration of a further dose of PPV to close contacts who have already received a dose of PPV more than two years previously is off-label but is recommended in accordance with the *UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings*. 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 consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration	Administer by intramuscular or subcutaneous injection. The preferred site is the deltoid region of the upper arm.

[10] Given the current UK supply shortages it is anticipated vaccine presented under the Pneumovax brand may enter the UK market. This PGD includes the provision of any PPV23 vaccine where it is recommended for administration as part of the national programme and brought to the UK market as a licensed product.

Continued over page **Route / method of administration** (continued)	The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously. However, for individuals with a bleeding disorder, vaccines may alternatively be given by subcutaneous injection to reduce the risk of bleeding. 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. The vaccine's normal appearance is a clear colourless solution. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: *www.medicines.org.uk*
Dose and frequency of administration	Single 0.5ml dose. Individuals with asplenia, splenic dysfunction or chronic kidney disease (see *Appendix A*) should be revaccinated at 5 year intervals. Close contacts of pneumococcal disease who have already received a dose of PPV more than two years previously should be offered a further dose of PPV in accordance with *UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings.* Revaccination is not routinely indicated for other individuals.
Duration of treatment	Single 0.5ml dose (see *Dose and frequency of administration* regarding indications for revaccination).
Quantity to be supplied / administered	Single 0.5ml dose.

Supplies	PPV is not centrally procured and therefore is not available through ImmForm. It should be ordered from the manufacturer/wholesalers. 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. PPV may be given at the same time as other vaccines. PPV can also be given at the same time as shingles vaccine, Zostavax®. Such administration is off-label but recommended in "*The Green Book*" following assessment of the evidence, concluding that there is no reduction in the effectiveness of Zostavax®.
Identification & management of adverse reactions	Local reactions following vaccination are very common including pain, swelling, induration and/or redness at the injection site. A low grade fever may occur. The most common systemic adverse events reported are asthenia/fatigue, myalgia and headache. Hypersensitivity reactions and anaphylaxis can occur but are very rare. Other adverse events have been reported in clinical trials and post-marketing surveillance but the frequency of these is not known. A detailed list of adverse reactions is available in the vaccine's SPC, which is 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* Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • *Splenectomy leaflet* *Available from: www.gov.uk/government/collections/immunisation*
Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. Vaccination may not result in complete protection in all recipients. Individuals at especially increased risk of serious pneumococcal infection (eg asplenics and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need for early antimicrobial treatment in the event of severe, sudden febrile illness. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.
Special considerations / additional information Continued over page **Special considerations / additional information**	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. Individuals who are a contact of pneumococcal disease do not usually require PPV. Immunisation may be indicated for close contacts where there is a confirmed cluster of serious pneumococcal disease in a closed setting and should be on the advice of your local Health Protection Team. Pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids. **Timing of vaccination** Wherever possible, immunisation or boosting of immunosuppressed or HIV-positive individuals should be either carried out before immunosuppression occurs or deferred until an improvement in immunity has been seen. The optimal timing for any vaccination

(continued)	should be based upon a judgement about the relative need for rapid protection and the likely response. For individuals due to commence immunosuppressive treatments, inactivated vaccines should ideally be administered at least two weeks before commencement. In some cases this will not be possible and therefore vaccination may be carried out at any time and re-immunisation considered after treatment is finished and recovery has occurred. Ideally PPV should be given four to six weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy. Where this is not possible, it can be given up to two weeks before treatment. If it is not practicable to vaccinate two weeks or more before splenectomy, immunisation should be delayed until at least two weeks after the operation. If it is not practicable to vaccinate two weeks or more before initiation of chemotherapy and/or radiotherapy, immunisation should be delayed until at least three months after completion of therapy in order to maximise the response to the vaccine. Immunisation of these individuals should not be delayed if this is likely to result in failure to vaccinate. Splenectomy, chemotherapy or radiotherapy should never be delayed to allow time for vaccination.
Records	Record: 8. that valid informed consent was given 9. name of individual, address, date of birth and GP with whom the individual is registered 10. name of immuniser 11. name and brand of vaccine 12. date of administration 13. dose, form and route of administration of vaccine 14. quantity administered 15. batch number and expiry date 16. anatomical site of vaccination 17. advice given, including advice given if excluded or declines immunisation 18. details of any adverse drug reactions and actions taken 19. supplied via PGD Records should be signed and dated (or a password controlled immuniser's

Continued over page **Records** (continued)	record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

- **Key references**

Key references	**Pneumococcal polysaccharide vaccine** • Immunisation Against Infectious Disease: The Green Book *Chapter 25* last updated 16 January 2018. *https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book* • Summary of Product Characteristic for pneumococcal polysaccharide vaccine, Merck Sharp & Dohme Limited. Last updated 30 April 2018. *http://www.medicines.org.uk/emc/medicine/1446* • NHS public health functions agreement 2017-18 Service specification No.8: Pneumococcal immunisation programme. Published April 2017. *https://www.england.nhs.uk/commissioning/pub-hlth-res/* • Enhanced Service Specification: Seasonal influenza and pneumococcal polysaccharide vaccination programme 2018/19. Published June 2018. *https://www.england.nhs.uk/publication/gp-contract-2017-18-enhanced-service-specifications/* **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*

- **Practitioner authorisation sheet**

PPV PGD v02.00 Valid from: 01/09/2018 Expiry: 31/08/2020

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 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 pneumococcal immunisation
(Green Book *Chapter 25* Table 25.1)

Clinical risk group	Examples (decision based on clinical judgement)
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. (Re-immunisation is recommended every 5 years)
Chronic respiratory disease	This includes chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema; and such conditions as bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children with respiratory conditions caused by aspiration, or a neurological disease (e.g. cerebral palsy) with a risk of aspiration. Asthma is not an indication, unless so severe as to require continuous or frequently repeated use of systemic steroids (as defined in Immunosuppression below).
Chronic heart disease	This includes those requiring regular medication and/or follow-up for ischaemic heart disease, congenital heart disease, hypertension with cardiac complications, and chronic heart failure.
Chronic kidney disease	Nephrotic syndrome, chronic kidney disease at stages 4 and 5 and those on kidney dialysis or with kidney transplantation. (Re-immunisation is recommended every 5 years)
Chronic liver disease	This includes cirrhosis, biliary atresia and chronic hepatitis.
Diabetes	Diabetes mellitus requiring insulin or oral hypoglycaemic drugs. This does not include diabetes that is diet controlled.
Immunosuppression	Due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, asplenia or splenic dysfunction, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement deficiency) Individuals on or likely to be on 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.

Individuals with cochlear implants	It is important that immunisation does not delay the cochlear implantation.
Individuals with cerebrospinal fluid leaks	This includes leakage of cerebrospinal fluid such as following trauma or major skull surgery.