**PHE publications gateway number: 2015326**

## PATIENT GROUP DIRECTION (PGD)

Administration of intradermal inactivated influenza vaccine (Intanza®) to individuals from 60 years of age in accordance with the national immunisation programme for active immunisation against influenza.

## This PGD is for the administration of intradermal inactivated influenza vaccine (Intanza®) by currently registered nurses, pharmacists[[1]](#footnote-2) or paramedics.

Reference no: Intanza PGD

Version no:v03.00

Valid from: 01 September 2017

Review date: 01 April 2018

Expiry date: 31 March 2018

**Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS 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]](#footnote-3). **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH** [**HMR2012 SCHEDULE 16 Part 2**](http://www.legislation.gov.uk/uksi/2012/1916/schedule/16/part/2/made)**.**

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.

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

**INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from:

<https://www.gov.uk/government/collections/immunisation>

Any concerns regarding the content of this PGD should be addressed to:

[immunisation@phe.gov.uk](mailto:Immunisation@phe.gov.uk)

# **Change history**

|  |  |  |
| --- | --- | --- |
| **Version number** | **Change details** | **Date** |
| V01.00 | New PHE PGD template | 18 August 2015 |
| V02.00 | PHE Intanza PGD amended to:   * reflect the unavailability of egg-free influenza vaccine (Optaflu®) in 2016/17 * reference the protocol for ordering storage and handling of vaccines * update wording regarding authorisation in line with agreed PHE PGD template changes * include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates | 9 August 2016 |
| V03.00 | PHE Intanza PGD amended to:   * remove text pertaining to non-payment for vaccinating morbidly obese individuals who are now included in the GP service specification * exclude patients who have received a dose of influenza vaccine for the current season * 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 * include minor typographical and layout changes in keeping with PHE PGD Policy | 04 July 2017 |

1. **PGD template development**

This PGD template 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 | C:\Users\beth.graham\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Word\Signature 1.jpeg | 04/07/2017 |
| Doctor | Mary Ramsay  Consultant Epidemiologist and Head of  Immunisation, Hepatitis & Blood Safety Department, PHE |  | 04/07/2017 |
| Registered Nurse (Chair of Expert Panel) | David Green  Nurse Consultant – Immunisations, PHE |  | 04/07/2017 |

This PGD template 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 Steering Group.

**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 |
| Matthew Olley | Immunisation Manager, Public Health England / NHS England London Region |
| Richard Pebody | Consultant Medical Epidemiologist, Public Health England |
| Lisa Rees | Medicines Management Pharmacist, Bristol Clinical Commissioning Group |
| 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 |

1. **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 …. |

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

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

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| **Qualifications and professional registration** | Registered professional with one of the following bodies:   * nurses currently registered with the Nursing and Midwifery Council (NMC) * pharmacists[[3]](#footnote-4) currently registered with the General Pharmaceutical Council (GPhC) * paramedics currently registered with the Health and Care Professions Council (HCPC) |
| **Additional requirements** | Additionally practitioners:   * must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction 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](https://www.nice.org.uk/guidance/mpg2/resources) for health professionals using patient group directions) * 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](https://www.gov.uk/government/collections/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 for Immunisation Training (2005)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/362171/National_Immun_Train_Stand1.pdf) * 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 Patient Group Direction 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. |

1. **Clinical condition or situation to which this PGD applies**

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| **Clinical condition or situation to which this PGD applies** | Intradermal influenza vaccine (Intanza®) is indicated for the active immunisation of patients for the prevention of influenza infection, in accordance with the national immunisation programme and recommendations given in [Chapter 19](https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19) of the Immunisation Against Infectious Disease: “The Green Book”, the [Flu Plan](https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan) and the [annual flu letter](https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan). |
| **Criteria for inclusion** | **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.**  Intanza® may be offered to individuals from 60 years of age eligible for vaccination as part of the 2017/18 national influenza immunisation programme ie:   * individuals aged 65 years or over (including those becoming age 65 years by 31 March 2018) * individuals from 60 years of age in a clinical risk group (see [Appendix A](#AppendixA)) 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+) * individuals from 60 years of age who are:   + 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.   + 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 workers from 60 years of age with direct patient/service user contact. These individuals should be vaccinated as part of an employer’s occupational health obligation (see [Flu Plan](https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan) Appendix D and [Chapter 12](https://www.gov.uk/government/publications/immunisation-of-healthcare-and-laboratory-staff-the-green-book-chapter-12)).   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](https://www.gov.uk/government/publications/immunisation-of-healthcare-and-laboratory-staff-the-green-book-chapter-12). |
| **Criteria for exclusion[[4]](#footnote-5)** | Patients for whom no valid consent has been received  Individuals who:   * are aged less than 60 years * have had a confirmed anaphylactic reaction to a previous dose of the vaccine or any component of the vaccine (including residues such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol 9) * are allergic to egg * have received a dose of influenza vaccine for the current season * 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** | Antibody response in patients with endogenous or iatrogenic immunosuppression may be suboptimal but it is still important to immunise this group. Very limited data in immunocompromised patients are available for Intanza®. |
| **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 a patient may have, as well as the risk of serious illness from flu itself. Where appropriate individuals should be referred or a PSD obtainedfor immunisation.  Where age is the exclusion criteria consider vaccination with live attenuated influenza vaccine (individuals aged 2 to 18 years) or intramuscular inactivated influenza vaccine as appropriate.  Individuals with severe anaphylaxis to egg which has previously required intensive care should be referred to specialists for immunisation in hospital.  Individuals with less severe egg allergy should be considered for vaccination with low-ovalbumin content intramuscular inactivated influenza vaccine in accordance with the advice in [Chapter 19](https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19) of “The Green Book” (see [PHE IM Influenza PGD template](https://www.gov.uk/government/publications/intramuscular-inactivated-influenza-vaccine-patient-group-direction-pgd-template)).  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 patient’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. |
| **Action to be taken if the patient or carer declines treatment**  Continued over page  **Action to be taken if the patient or carer declines treatment**  (continued) | Informed consent, from the individual or a person legally able to act on the person’s behalf, must be obtained for each administration.  Advise 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. |

**Continued over page**

1. **Description of treatment**

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| **Name, strength & formulation of drug** | Intanza® 15 microgram/strain (inactivated influenza vaccine) suspension for intradermal injection in a pre-filled syringe with a micro-injection system. |
| **Legal category** | Prescription only medicine (POM). |
| **Black triangle▼** | No. |
| **Off-label use** | No. |
| **Route / method of administration** | Administer by intradermal injection, preferably into deltoid region of the upper arm.  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 is a colourless opalescent suspension. It should not be used if foreign particles are present in the suspension.  It is not necessary to shake the vaccine before use.  To administer the micro-injection system (see SPC for pictorial instructions):   * + - * remove the needle cap       * hold micro-injection system between thumb and middle finger       * insert needle rapidly, perpendicular to the skin       * inject using index finger       * remove needle from skin       * orientate the needle away from you and others       * activate needle shield by pushing firmly on plunger   In case of presence of liquid at the injection site after vaccine administration, re-vaccination is not required.  The SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) |
| **Dose and frequency of administration** | Single 0.1ml dose to be administered for the current annual flu season. |
| **Duration of treatment** | Single 0.1ml dose for the current annual flu season. |
| **Quantity to be supplied / administered** | Single dose of 0.1ml dose 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 patient age groups (Intanza® 15 microgram/strain is licensed from 60 years of age).  Providers should order vaccine for those aged 65 years and older and those in adult clinical risk groups from the influenza vaccine manufacturers as in previous years.  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](https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines) and Green Book [Chapter 3](https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-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. |
| **Disposal** | Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant ‘sharps’ box, according to local authority regulations and guidance in the [technical memorandum 07-01](https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste): 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.  May be given at the same time as other vaccines.  A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://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. A small painless nodule (induration) may also form at the injection site.  In trials local reactions after intradermal administration were more frequent than after intramuscular administration of an adjuvanted or non-adjuvanted comparator vaccine. Most reactions resolved spontaneously within 1 to 3 days after onset.  Allergic reactions can occur including generalised skin reactions such as urticaria, anaphylactic reactions, angioedema and shock.  A detailed list of adverse reactions is available in the SPC for the vaccine, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) |
| **Reporting procedure of adverse reactions** | Healthcare professionals and patients/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 marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. |
| **Patient advice / follow up treatment**  continued over page  **Patient advice / follow up treatment**  (continued) | Patients 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 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 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. |
| **Records** | Record:   * that valid informed consent was given; * name of patient, address, date of birth and GP with whom the patient 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 Patient Group Direction (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 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 patient records.  It is important that vaccinations given either at a general practice or elsewhere 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 patient’s general practice to allow clinical follow up and to avoid duplicate vaccination.  A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy. |

1. **Key references**

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| **Key references** | **Intradermal influenza vaccine (Intanza®)**   * Immunisation Against Infectious Disease: The Green Book, [Chapter 19](https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19). Published 28 August 2015   <https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19>   * Collection: Annual Flu Programme   <https://www.gov.uk/government/collections/annual-flu-programme>   * Flu Plan: Winter 2017 to 2018. Published 20 March 2017   https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan   * The national flu immunisation programme 2017 to 2018: supporting letter. Published 20 March 2017   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 for Intanza® 15 micrograms/strain, Sanofi Pasteur, 18 January 2017   <http://www.medicines.org.uk/emc/medicine/21744>  **General**   * PHE Immunisation Collection <https://www.gov.uk/government/collections/immunisation> * British National Formulary (BNF) and British National Formulary for Children (BNF-C) [www.BNF.org](http://www.BNF.org)   [http://www.evidence.nhs.uk/formulary/bnf/current](http://www.evidence.nhs.uk/formulary/bnf/current/14-immunological-products-and-vaccines/144-vaccines-and-antisera/influenza-vaccines)   * National Minimum Standards for Immunisation Training (2005) <https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards> * 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> * Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. <https://www.rcn.org.uk/professional-development/publications/pub-005336> * Protocol for ordering storage and handling of vaccines. April 2014.   <https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>   * 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> |

1. **Practitioner authorisation sheet**

**Intanza PGD v03.00 Valid from: 01/09/2017 Expiry: 31/03/2018**

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.

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| 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 |
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**Authorising manager**

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| --- | --- | --- | --- |
| 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.

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| **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. |

1. This may include pharmacists working for primary care providers or community pharmacists who have been locally commissioned. This PGD is not authorised for the national community pharmacy seasonal influenza vaccination advanced service which has its own PGD (see Pharmacy Influenza Vaccination PGD). [↑](#footnote-ref-2)
2. This includes any relevant amendments to legislation (eg [2013 No235](http://www.legislation.gov.uk/uksi/2013/235/contents/made), [2015 No.178](http://www.legislation.gov.uk/nisr/2015/178/contents/made) and [2015 No.323](http://www.legislation.gov.uk/uksi/2015/323/contents/made)). [↑](#footnote-ref-3)
3. This may include pharmacists working for primary care providers or community pharmacists who have been locally commissioned. This PGD is not authorised for the national community pharmacy seasonal influenza vaccination advanced service which has its own PGD (see Pharmacy Influenza Vaccination PGD). [↑](#footnote-ref-4)
4. 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 [↑](#footnote-ref-5)