



PATIENT GROUP DIRECTION (PGD)

Administration of intramuscular inactivated influenza vaccine

Individuals in accordance with the national immunisation programme

For the administration of intramuscular inactivated influenza vaccine by currently registered nurses, midwives, pharmacists or paramedics to individuals in accordance with the national immunisation programme for active immunisation against influenza.

Reference no: *IM Influenza PGD*
Version no: *v01.00 (National Community Pharmacy Advanced Service)*
Valid from: *1 September 2015*
Review date: *1 March 2016*
Expiry date: *31 August 2016*

Public Health England has developed this PGD for authorisation by NHS England to facilitate delivery of the national immunisation programme.

Those using this PGD must ensure that it is formally authorised and signed by a clinical governance or patient safety lead, who has designated responsibility for signing PGDs on behalf of NHS England, so that this document meets legal requirements for a PGD. **THE PGD IS NOT LEGAL OR VALID WITHOUT THIS FORMAL AUTHORISATION.**

Authorising organisations must not alter or amend the body of this document; such action will invalidate the clinical sign-off with which it is provided.

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

THE PRACTITIONER 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:

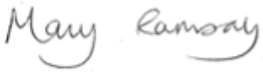
Immunisation@phe.gov.uk

Change History

Version number	Change details	Date
V01.00	New PHE PGD template	18 August 2015
V01.00 (National Community Pharmacy Advanced Service)	Front page and page 4 amended to reflect national NHS England authorisation for delivery of the national Community Pharmacy Advanced Service	03 September 2015

1. PGD Template Development

This PGD template has been developed by the following on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		08/09/2015
Doctor	Mary Ramsay Consultant Epidemiologist and Head Immunisation, Hepatitis & Blood Safety Department, PHE		08/09/2015
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This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE Policy for PGD Templates. It has been ratified by PHE Medicines Management Group and PHE Clinical Governance Group.

Acknowledgements

Name	Designation
Dr Richard Pebody	Consultant Medical Epidemiologist, Head of Influenza Surveillance and Acting Head of Respiratory Diseases, Centre for Infectious Disease Surveillance and Control
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Sue Mulvenna	Pharmacist Lead - NHS England South West
Graham Munslow	Clinical Screening and Immunisation Manager, NHS England Lancashire & Greater Manchester / Public Health England.
Sharon Webb	Programme Manager - IDPS , NHS Screening Programmes, Public Health England (Midwife)

2. Organisational Authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Community Pharmacies delivering the Community Pharmacy Seasonal Influenza Vaccination Advanced Service and meeting all of the requirements for this service outlined in the service specification.
Limitations to authorisation
The Community Pharmacy Seasonal Influenza Vaccination Advanced Service Specification, Annex A defines groups to be included in the advanced service and these are covered by this PGD authorisation. This PGD authorisation does <u>not</u> cover under 18s or those who are morbidly obese, although many of this patient group will already be eligible due to complications of obesity that place them in another risk category.

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Head of Primary Care Commissioning, NHS England	David Geddes		04/09/2015

Enquiries regarding the use of this PGD may be directed to:

england.primarycareops@nhs.net

Organisations must add an individual practitioner authorisation sheet or list of authorised practitioners. This varies according to local policy but this should be a signature list or an individual agreement 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). • Paramedics currently registered with the Health and Care Professions Council (HCPC).
Additional requirements	• 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 for health professionals using patient group directions). • Must be familiar with the vaccine product and alert to changes in Summary Product Characteristics, 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). • 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. • Have access to the Patient Group Direction and associated online resources. • Should fulfil any additional requirements defined by local policy. THE 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 the 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 patients 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 Flu Plan and the annual flu letter.
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 (eg only adults) this PGD does not constitute permission to offer influenza immunisation beyond the groups they are commissioned to immunise. In 2015/16, flu vaccinations should be offered at NHS expense to the following groups: • people aged 65 years or over (including those becoming age 65 years by 31 March 2016) • 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) • all pregnant women (including those women who become pregnant during the flu season) • people living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions or university halls of residence. • people who are in receipt of a carer’s allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill. • household contacts of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and therefore for whom continuing close contact is unavoidable. • The PGD includes vaccination of individuals who are morbidly obese (defined as BMI 40+) as these people could also benefit from a flu vaccination. However, vaccination of morbidly obese patients with no other recognised risk factor will not attract a payment under the Directed Enhanced Service (DES) in 2015/16 (See Additional Information Section).

Criteria for exclusion¹	• Patients for whom no valid consent has been received People 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 (other than ovalbumin – see Cautions). • Have had a severe anaphylactic reaction to egg which has previously required intensive care, if the egg-free product (Optaflu®) is unavailable or the patient is too young to receive it (ie under 18 years of age). • Are aged 2 years to under 18 years for whom Fluenz Tetra® ▼ is NOT contraindicated (ie Fluenz Tetra® ▼ should be given in preference to inactivated influenza vaccine). Exclusions from PGD The indications for flu vaccination are not exhaustive, and the healthcare practitioner should apply clinical judgement to take into account the risk of flu exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from flu itself. Flu vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above – A Patient Specific Direction (PSD) will be required. Occupational health provision of influenza vaccine Health and social care staff directly involved in the care of their patients or clients – vaccination should be provided via the employers occupational health arrangements. This is outside the remit of this PGD. Temporary Exclusion Administration of inactivated influenza vaccine should be postponed in patients 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)	For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see “The Green Book” Chapter 4). Egg Allergy The ovalbumin-free influenza vaccine Optaflu®, if available, can be used in any setting for patients from the age of 18 years, regardless of the severity of the egg allergy. Patients can also be immunised in any setting using an inactivated influenza vaccine with an ovalbumin content less than 0.12 µg/ml (equivalent to 0.06 µg for 0.5 ml dose), excepting those with severe anaphylaxis to egg which has previously required intensive care (See Criteria for exclusion). In 2015/16 Fluarix® Tetra ▼ and

¹ 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

Cautions including any relevant action to be taken (continued)	inactivated influenza vaccine (split virion) BP contain less than 0.12µg/ml ovalbumin. 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	Seek appropriate advice from the local Screening and Immunisation Team, a Consultant in Health Protection or the individual's clinician, as a PSD may be indicated. The risk to the individual of not being immunised must be taken into account. Egg allergy Individuals with severe anaphylaxis to egg which has previously required intensive care should receive the ovalbumin-free influenza vaccine Optaflu[®] if they are 18 years or over. If this is not available or they are less than 18 years of age they should be referred to specialists for immunisation in hospital. Document reason for exclusion and any action taken in patient's clinical records. In a GP practice setting, inform or refer to the GP or a prescriber. Temporary exclusion In case of postponement due to acute illness, advise when they can be vaccinated and ensure another appointment is arranged.
Action to be taken if the patient or carer declines treatment	Informed consent, from the patient or a person legally able to act on the patient's behalf, must be obtained for each administration. Advise patient/carers about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and decision reached. In a GP practice setting, inform or refer to the GP.
Arrangements for referral for medical advice	As per local policy.

5. Description of Treatment

Name, strength & formulation of drug	Inactivated influenza vaccine suspension in a pre-filled syringe. (This PGD does NOT cover the use of the intradermal vaccine Intanza®.) A list of the influenza vaccines available in the UK is published ahead of the influenza season in the annual flu letter for England.
Legal category	Prescription Only Medicine (POM).
Black triangle▼	Fluarix® Tetra▼ is black triangle.
Off-label use	Administration of Fluarix® Tetra▼ or Optaflu® by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 of “The Green Book”. Note: Different influenza vaccines are licensed from different ages and should be administered within their licence when working to this PGD. Refer to products Summary of Product Characteristics (SPC) at www.medicines.org.uk and the list of the influenza vaccines available in the UK for 2015-2016 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. 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. For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see Green Book Chapter 4). The vaccine should be allowed to reach room temperature before use. Shake vaccine before administration. Inspect visually prior to administration and ensure appearance is consistent with description in Summary of Product Characteristics. The Summary of Product Characteristics provide further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk
Dose and frequency of administration (continued over page)	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. JCVI has advised that when a choice of either a 0.25ml or 0.5ml dose

Dose and frequency of administration (continued)	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. Preferred vaccine choice for children <table border="1"> <thead> <tr> <th>Age</th><th>Recommended influenza vaccine</th></tr> </thead> <tbody> <tr> <td>6 months to less than 2 years</td><td>Offer trivalent inactivated influenza vaccine Note: Fluenz Tetra[®]▼ intranasal vaccination and quadrivalent inactivated influenza vaccine (Fluarix[™] Tetra▼) are not licensed in this age group.</td></tr> <tr> <td>2 years to under 3 years of age</td><td>Offer Fluenz Tetra[®]▼ intranasal vaccination unless medically contraindicated (see Fluenz Tetra[®]▼ PGD). Otherwise, these children should be given an inactivated trivalent vaccine. Note: The quadrivalent inactivated influenza vaccine (Fluarix[®] Tetra▼) is not licensed in this age group</td></tr> <tr> <td>3 years to under 18 years of age</td><td>Offer Fluenz Tetra[®]▼ intranasal vaccination unless medically contraindicated (see Fluenz Tetra[®]▼ PGD). The quadrivalent inactivated influenza vaccine (Fluarix[®] Tetra) is licensed for children from the age of three years and is preferred over the trivalent vaccine because of the additional protection offered. Otherwise, children should be given an inactivated trivalent vaccine.</td></tr> </tbody> </table>	Age	Recommended influenza vaccine	6 months to less than 2 years	Offer trivalent inactivated influenza vaccine Note: Fluenz Tetra [®] ▼ intranasal vaccination and quadrivalent inactivated influenza vaccine (Fluarix [™] Tetra▼) are not licensed in this age group.	2 years to under 3 years of age	Offer Fluenz Tetra [®] ▼ intranasal vaccination unless medically contraindicated (see Fluenz Tetra [®] ▼ PGD). Otherwise, these children should be given an inactivated trivalent vaccine. Note: The quadrivalent inactivated influenza vaccine (Fluarix [®] Tetra▼) is not licensed in this age group	3 years to under 18 years of age	Offer Fluenz Tetra [®] ▼ intranasal vaccination unless medically contraindicated (see Fluenz Tetra [®] ▼ PGD). The quadrivalent inactivated influenza vaccine (Fluarix [®] Tetra) is licensed for children from the age of three years and is preferred over the trivalent vaccine because of the additional protection offered. Otherwise, children should be given an inactivated trivalent vaccine.
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Duration of treatment	Single 0.5ml dose annually 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	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. 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. For children under 18 years of age where Fluenz Tetra[®]▼ is medically contraindicated an inactivated trivalent vaccine or Fluarix[®] Tetra▼ will be supplied. These vaccines should be ordered as per the usual mechanisms for the routine childhood immunisation programme.								

Storage	Store in a refrigerator 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 proper, 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 interactions²	Immunological response may be diminished in those receiving immunosuppressive treatment. May be given at the same time as other vaccines.
Identification & management of adverse reactions²	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 detailed list of adverse reactions associated with inactivated influenza vaccine is available in the Summary of Product Characteristics for each vaccine, which are available from the electronic Medicines Compendium website: 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 Fluarix [®] Tetra▼ is black triangle. Therefore, <i>any</i> suspected adverse reactions should be reported via the National Reporting System and 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.

² Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Patient advice / follow up treatment	Patients should be advised that many other organisms cause respiratory infections similar to influenza during the influenza season, eg the common cold and respiratory syncytial virus. Influenza vaccine will not protect against these diseases. Inform patient/parent/carer of possible side effects and their management. The patient/parent/carer should be advised to seek medical advice in the event of an adverse reaction. When applicable, advise patient/parent/carer when a subsequent vaccine dose is due. When administration is postponed advise the patient/parent/carer when to return for vaccination.
Special considerations / additional information	Immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. 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. The JCVI advised that morbidly obese people (defined as BMI 40+) could also benefit from a flu vaccination. This has not been included as part of the GP contract in the 2015/16 DES. Many in this patient group will already be eligible due to complications of obesity that place them in another risk category. Providers will need to decide whether to vaccinate this group of patients, but vaccinations for morbidly obese patients with no other recognised risk factor will not attract a payment under the DES in 2015/16. The quadrivalent inactivated influenza vaccine (Fluarix[®] Tetra▼) is authorised for children from the age of three years and is preferred because of the additional protection offered. The quadrivalent vaccine has both lineages of influenza B and may therefore provide better protection against the circulating B strain(s) than trivalent inactivated influenza vaccines. Due to the risk of febrile convulsions, the indication for Enzira[®] is restricted to use in adults and children aged five years and older. The SPC for Enzira[®] 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 2015/16 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: • Influvac[®], Imuvac[®], Agrippal[®] and inactivated influenza vaccine (split virion) BP may be given from 6 months of age within the product licence. • Pfizer vaccines bioCSL generic and Enzira[®] are licensed from 5 years of age. • Fluarix[®] Tetra▼ is licensed from 3 years of age. • Optaflu[®] is licensed from 18 years of age.

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 • Record 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 (for example, at community pharmacies, or antenatal clinics) are recorded on appropriate health records for the individual (using the appropriate clinical code) in a timely manner, including the relevant Child Health Information System. 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.
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6. Key References

Key references	Inactivated influenza vaccination - Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 21 May 2015 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147958/Green-Book-Chapter-19-v4_71.pdf - Collection: Annual Flu Programme https://www.gov.uk/government/collections/annual-flu-programme - Flu Plan: Winter 2015 to 2016. Published 27 March 2015 https://www.gov.uk/government/publications/flu-plan-2015-to-2016 - The national flu immunisation programme 2015 to 2016: supporting letter. Published 27 March 2015 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/418428/Annual_flu_letter_24_03_15_FINALv3_para9.pdf - Influenza vaccines 2015 to 2016 flu season https://www.gov.uk/government/publications/influenza-vaccines-2015-to-2016-flu-season - Summary of Product Characteristics www.medicines.org.uk 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 https://www.evidence.nhs.uk/formulary/bnf/current/14-immunological-products-and-vaccines/144-vaccines-and-antisera/influenza-vaccines/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 https://www.nice.org.uk/guidance/mpg2 - NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions https://www.nice.org.uk/guidance/mpg2/resources/competency-framework-for-health-professionals-using-patient-group-directions-60468733 - Competency Framework – assessment tool (Appendix). Supporting the delivery of immunisation education. Royal College of Nursing (RCN) 2013. http://www.rcn.org.uk/_data/assets/pdf_file/0005/553748/004479.pdf - 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
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7. Individual Practitioner Authorisation Sheet

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

Practitioner

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

Signed.....Date.....

Name (Print)

Designation.....

Authorising Manager

Manager to give authorisation on behalf of **INSERT NAME OF ORGANISATION** for the named Health Care Professional who has signed the PGD

Signed..... Date.....

Name (Print).....

Designation.....

Note to Authorising Manager

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so

You must give this signed PGD to each Authorised Practitioner as it shows their authorisation to use the 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 decisions should be 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/m ²

*Many of this patient group will already be eligible due to complications of obesity that place them in another risk category