Family Nursing & Home Care	**Family Nursing & Home Care** Patient Group Direction Administration of **Inactivated Influenza Vaccine** (intramuscular or subcutaneous)	**PGD No:10** Issue Date: 25·09·2017 Review Date: JUNE 2020

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by the organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Division/Department: All Clinical Areas

1. Clinical Condition:

1.1	Define situation/condition	Inactivated influenza vaccine is indicated for the active immunisation of individuals for the prevention of influenza infection.
1.2	Criteria for inclusion	Should be offered to all health and social care workers including staff in high risk groups such as: • All those aged 65 years or over (including those becoming age 65 years by 31 March 2018) • all pregnant women (including those women who become pregnant during the flu season) • All those in the clinical risk groups listed below: o chronic (long-term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis o chronic heart disease, such as heart failure o chronic kidney disease at stage three, four or five o chronic liver disease o chronic neurological disease, such as Parkinson's disease or motor neurone disease, or learning disability o diabetes type 1 and 2 including diet controlled diabetes o asplenia or splenic dysfunction o a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment) o 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) consideration should also be given to the vaccination of household contacts of immunocompromised individuals o morbidly obese (defined as BMI 40+) o other groups/individuals considered at clinical risk as listed within the Consultant in Communicable Disease Control (CCDC's) annual influenza letter.

1.3	Criteria for exclusion	• Individuals for whom no valid consent has been received
		• People who:
		  • 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 and Warnings).
		  • have had a severe anaphylactic reaction to egg which has previously required intensive care
		  • have received a dose of influenza vaccine for the current season
		• For full details/information of contraindications, refer to the marketing authorisation holder's SPC available at: http://www.medicines.org.uk
		Temporary exclusion
		• Acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation). If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.

1.4	Cautions/warnings	• 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). Please note, in this context, bleeding disorder does not mean individuals on aspirin or therapeutically controlled warfarin management. **Egg Allergy** • 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). Detailed information on the characteristics of the available vaccines for the current 'flu season, including ovalbumin content is published on the Public Health England immunisation web pages https://www.gov.uk/government/collections/immunisation • Syncope (fainting) can occur following, or even before, any vaccination 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. • For full details/information of cautions, warnings and drug interactions, refer to the marketing authorisation holder's SPC available at: http://www.medicines.org.uk • Store at +2°C to +8°C. • Store in original packaging in order to protect from light.

		• Do not freeze. • Immunological response may be diminished in those receiving immunosuppressive treatment but it is important to still immunise this group. • Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.
1.5	Action if patient 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 to their GP. • Individuals with severe anaphylaxis to egg which has previously required intensive care should be referred to specialists for 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 on the consent form • Seek appropriate advice from the HSSD Staff Immunisation Nurse, HSSD Immunisation Nurse Specialist, The HSSD Head of Preventative Programmes or the individual's GP as required.
1.6	Action if patient declines	• Informed consent from the individual must be obtained prior to administration of the vaccine. • Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease. • Advise to contact the FNHC Nurse Immuniser, HSSD Immunisation Nurse Specialist or their GP if wishes to discuss further in the future. • Document advice given and the decision reached on the consent form.

2. Characteristics of Staff

2.1	Class of Health Professional for whom PGD is applicable	Jersey Registered Nurse employed by Family Nursing & Home Care.
2.2	Additional requirements considered relevant to the medicines used in the PGD	• Has successfully completed, within the last 3 years, the FNHC e-Learning package for working under PGD's for the supply and administration of medicines • Has undertaken annual practical training in adult basic life support and successfully completed the annual e.learning training and assessment for the recognition and treatment of anaphylaxis.

		• Must have access to a current copy of the *Immunisation against infectious disease* (Green book) and comply with its recommendations (see DH Website – www.dh.gov.uk/greenbook). 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 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 the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ("The Green Book"), and national and local immunisation programmes • 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
2.3	Continued training requirements	• Complete the FNHC PGD e.learning training every 3 years • Undertake annual adult basic life support training • Undertake annual training in the recognition and management of anaphylaxis. • 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.

3. Description of Treatment

3.1	Name of Medicine and pharmaceutical form(s)	Inactivated influenza vaccine suspension in a pre-filled syringe. A list of influenza vaccines available in the UK for the current 'flu season is published on the Public Health England website https://www.gov.uk/government/organisations/public-health-england .
3.2	Legal Status	Prescription only medicine (POM). (for black triangle (▼) status check individual summary of product characteristics at www.medicines.org.uk)
3.3	Licensed or Unlicensed	Licensed *Off Label Use*

		• Administration of Fluarix® Tetra▼ 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". • Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
3.4	Dose(s)	Single 0.5ml dose to be administered for the current annual flu season.
3.5	Frequency	Single 0.5ml dose annually.
3.6	The maximum total dose or number of times treatment can be administered, and over what period of time	Single 0.5ml dose annually.
3.7	Route/Method of Administration	• Administer by intramuscular injection, preferably into deltoid region of the upper arm • 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). • 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 • Dispose of used vaccine syringes and needles into a 'sharps' box' according to local policy
3.8	Side effects (to include potential adverse reactions) and any monitoring required	• 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. • For full details/information on possible side effects/adverse reactions, refer to the marketing authorisation holder's SPC which is available from the Medicines Compendium website: www.medicines.org.uk • All vaccine recipients will be observed for a few minutes after the vaccination if they are in any way unwell.
3.9	Written/Verbal advice for patient/carer before/after treatment	• Inform of possible commonly reported side effects and their management.

		• Advise individual to seek immediate medical attention in the case of severe adverse reaction. • When administration is temporarily postponed, advise the individual when to return for vaccination. • Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. • 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.
3.10	Procedure for reporting ADRs to Doctor	• Any serious adverse reaction to the vaccine should be reported to the MHRA via the yellow card system at www.yellowcard.gov.uk • For black triangle drugs (▼) ***any*** suspected adverse reactions should be reported to the MHRA via the yellow card system. • In the event of a severe adverse reaction requiring attendance at hospital, a letter giving details of event should be sent with the patient. The nurse giving the vaccination will retain the responsibility to report the reaction to the MHRA. • The individual's GP should be informed of any adverse reaction with their consent. • Any definite or suspected adverse drug reactions should also be reported to the Consultant Microbiologist.
3.11	Specify method of recording of supply/administration	For staff 'flu immunisation, the following information to be recorded on the vaccine consent form: • name of person being vaccinated • date of birth • name and brand of vaccine given • dose given • date of vaccination • batch number • expiry date • administration route (including site of injection) • That a PGD was used • Information/advice given • full name and signature of practitioner administering the vaccine

Key References

Adapted from Public Health England's Patient Group Direction for Administration of intramuscular (or subcutaneous) inactivated influenza vaccine to individuals in accordance with the national immunisation programme for active immunisation against influenza available at https://www.gov.uk/government/publications/intramuscular-inactivated-influenza-vaccine-patient-group-direction-pgd-template and local States of Jersey Health and Social Services Department Patient Group Directions "Administration of Seasonal Flu Vaccine" (approved and authorised 04/08/17) and "Administration of Influenza (Flu) Vaccine" (final draft version)

Inactivated influenza vaccination

- Immunisation Against Infectious Disease: The Green Book, Chapter 19. Published 28 August 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 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 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 http://www.evidence.nhs.uk/formulary/bnf/current
- 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
- Yellow card adverse event reporting system available at http://yellowcard.mhra.gov.uk

Change History

Date	Number	Change
2012	1.2	Expanded list of possible recipients – no longer just for staff.
	1.3	Changes to the exclusion criteria and websites to consult for further information.
	1.6	Added - Inform GP if applicable
	2.1	Now includes intradermal injections.
	3.2	Includes information regarding black triangle medicines.
	3.4	Includes dosages for children.
	3.5	Includes information re frequency in children.
	3.6	Includes information regarding total dose for children.
	3.7	Includes anterolateral thigh and use of the deep subcutaneous route for those with bleeding disorders. Intra dermal injections.
	3.9	Removed – warning re other causes of respiratory infections.
	3.10	Report adverse drug reactions to MHRA not CSM. Yellow card also available on line
	3.11	Includes full name of person administering as well as signature. Includes name of recipient, date of birth and URN. No longer specifies healthcare workers as only recipients.

Date	Number	Change
October 2014 (to reflect the HSS seasonal influenza PGD signed in April 2014)	1.2	'people who work in close contact with poultry' has been removed from the inclusion criteria
	3.4	The dose specified for adults now includes children over 9 years of age The children's age range is now from 3 to 9 years rather than from 3 to 12 years
	3.5	Changes to children's age ranges: • Children over 9 years rather than over 13 years • Children aged 6 months up to 9 years rather than children 12 years and under
	3.6	Changes to children's age ranges: • Children over 9 years rather than over 13 years • Children aged 6 months up to 9 years rather than children 12 years and under
	3.7	Wording changed regarding the preferred site for injection Preferred site for injection for infants now stated
	3.8	'Allergic reactions leading to shock' removed from 'Rare Side Effects'
	3.11	Wording changed to reflect the recording of information on the vaccine consent form

August 2016 Review

No changes made at this review.

This Patient Group Direction (PGD) is to be reviewed in one year rather than the usual 2 years so it remains in line with Health and Social Services who will be reviewing their Seasonal Influenza PGD next year.

Date	Number	Change
September 2017	Updated FNHC PGD template used	
	1.2	Inclusion criteria amended to reflect that the PGD is only for staff prophylactic 'flu immunisation.
	1.3	No valid consent added Reference to children removed Anaphylaxis due to egg clarified and reference to chicken protein removed Dose of 'flu vaccine already received for the current season added Standard statement re contraindications plus web link to electronic medicines compendium
	1.4	Standard statement re cautions, warnings and drug interactions plus web link to electronic medicines compendium Details re egg allergy added Syncope risk added

Date	Number	Change
		Storage requirements added Immunological response added
	1.5	Consideration to the risk of not immunising added Action in the case of previous severe anaphylaxis to egg added Document reason for exclusion on the consent form added Where to seek advice has been included.
	1.6	Additional advice for the individual included Advice given to be documented on the consent form
	2.1	Class of health professional standardised in line with other FNHC PGDs
	2.2	Updated in line with Public Health England's PGD for 'flu immunisation and other FNHC PGDs
	3.3	Off label use added
	3.4	Only dose to be administered to cohort in inclusion criteria is included
	3.5	Only adult dose for cohort in inclusion criteria used
	3.6	Only maximum for cohort in inclusion criteria used
	3.7	Visual inspection and shaking of vaccine prior to use added Reference to Summary of Product Characteristics added Storage now detailed in 1.4
	3.8	Rare and very rare side effects no longer detailed Standard statement re accessing SPC and web link to the electronic medicines compendium added as per other FNHC PGDs If in any way unwell, vaccine recipients to be observed for a few minutes.
	3.9	Advice if severe adverse reaction added Advice added that vaccine cannot cause influenza however, it does not protect against other respiratory viruses. Advice for immunosuppressed individuals has been added
	3.10	With the individual's consent any adverse reaction should be reported to their GP In the case of a severe adverse reaction requiring hospital admission, the nurse is responsible for reporting the reaction to the MHRA.
	3.11	That a PGD was used and any advice/information given has been added

4. Management of Patient Group Direction:

I Developed by:		
	Name	**Signature**
Senior Doctor	Sarah Whiteman (Medical Director, Primary Care)	
Senior Pharmacist	Sara Kynicos (Pharmacy Advisor to Family Nursing & Home Care)	
Senior Health Professional	Elspeth Snowie (Clinical Effectiveness Facilitator)	
Other (please specify		

II Approved by CEO of Family Nursing & Home Care		
	Name	**Signature**
Chief Executive Officer	Judy Foglia (Acting Chief Executive Officer)	
Date of Approval		

III Authorised by the Minister for Health		
	Name	**Signature**
Minister for Health	Andrew Green	
PGD Number	**10**	
Date of Authorisation	25.09.2017	
Date for Commencement of Review	JUNE 2020	
Last Date for Reauthorisation	24.09.2020	

Plan a review to enable completion prior to the date above and date the new protocol to follow on immediately, also retain a copy of each version of the protocol for ten years.