PATIENT GROUP DIRECTION (PGD)

Administration of Inactivated Influenza Vaccine 2013/14 season

For the supply and administration of inactivated Influenza vaccine by nurses currently registered with the Nursing and Midwifery Council (NMC) and other registered professionals commissioned by the NHS England Area Team to eligible individuals identified in accordance with the current National Immunisation Programme (Chapter 19 of the Green Book (updated 11th September 2013) and the Tripartite Letter https://www.gov.uk/government/publications/flu-immunisation-programme-2013-to-2014)

Reference no:

Influenza PGD

Version no:

1.0

Valid from:

September 2013

Review date:

July 2014

Expiry date:

August 2014

Following authorization by NHSE Area Team as the Commissioner, each organization using this PGD must ensure that it is formally authorized and signed by a governance lead for the organization so that this document meets legal requirements for a PGD. The PGD is not legal or valid without this local, formal authorization.

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

1. Clinical condition or situation to which the direction applies

Indication	Immunisation against seasonal influenza in accordance with the current National Immunisation Programme.
Objective of programme	The objective of the National Flu immunisation programme is to protect those people who are most at risk of serious illness or death should they develop influenza and reduce the transmission of infection by giving a minimum of one dose of an influenza vaccine to individuals aged 6 months and over in one or more of the groups specified by the National Programme.
Criteria for inclusion	The Department of Health guidelines for 2013/14 influenza campaign is that

the seasonal influenza vaccine should be offered to the following groups

Group 1: All those aged 65 years and over on 31 March 2014 (i.e. born on or before 31 March 1949).

Group 2: All those aged 6 months or over in a clinical risk group; for a list of clinical risk groups, see **Appendix 1**.

<u>Please note</u>: Fluenz® is the recommended vaccine for patients aged between 2 and 17 years. (See Fluenz® PGD for further guidance.) If insufficient supplies of Fluenz® then it is acceptable to use an inactivated influenza vaccine suitable for the age of the child (see Appendix 3)

Group 3: Those 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.

Group 4: Those 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. This should be given on an individual basis at the GP's discretion.

Group 5: Pregnant women at any stage of pregnancy (first, second or third trimester).

Other Groups

Risk of Serious illness:

As well as offering influenza vaccine to people in the clinical risk groups (Appendix 1), GPs should take into account the risk of influenza infection exacerbating any other underlying disease that a patient may have, as well as the risk of serious illness from influenza itself. GPs should offer influenza vaccine in such cases based on an assessment of clinical needs of individual patients, even if the individual is not in the clinical risk groups mentioned above.

Healthcare workers

Health and Social Care providers/organisations should encourage employees who have patient contact to have the influenza vaccination.

NO EXCLUSION CRITERIA SHOULD APPLY TO ANY OF THE ABOVE (see below)

Criteria for Exclusion¹

Please note:

Fluenz® is the vaccine of choice for children aged 2-17 years as it has been shown to provide a higher level of protection for children than inactivated influenza vaccine. GPs will need to order sufficient supplies of Fluenz® for this group of individuals. Fluenz®, however, is unsuitable for children under 2 years of age. It is also unsuitable for individuals with contraindications such as severe immunodeficiency or egg allergy. Please refer to Fluenz® PGD and Manufacturers SPC for further guidance. Where insufficient supplies of Fluenz® exist, then it is acceptable to use an inactivated influenza vaccine suitable for the age of the child (See Appendix 3).

- Infants under 6 months
- Further age restrictions for specific brands of inactivated flu vaccines
 - Enzira® and CSL Inactivated Influenza Vaccine (CSL Biotherapies) exclude children under 5 years with caution for children aged between 5 and 9 years (possible increased risk of febrile convulsions)
 - Viroflu® exclude children under 5 years (higher rate of fever)
 - Fluvirin® exclude children under 4 years

Page 2 of 14

¹ Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it would be outside the remit of the PGD and another form of authorisation will be required.

	(other than ovalbumin – see below). Different brands may contain traces of neomycin, gentamicin, kanamicin and other excipients –
	 A confirmed anaphylactic reaction to any component of the vaccine (other than ovalbumin – see below). Different brands may contain traces of neomycin, gentamicin, kanamicin and other excipients – check the brand being used at www.medicines.org.uk or the package
	 insert. Patients who have confirmed anaphylaxis to egg or egg allergy with
	uncontrolled asthma (BTS SIGN step 4 or above) – all egg containing vaccines are contraindicated. (Patients should be referred to specialist for vaccination in hospital using vaccine with an ovalbumin content less
	than 0.12 micrograms/ml i.e. less than 0.06 micrograms per 0.5ml dose).
	Other egg allergic individuals – vaccines with ovalbumin content more than 0.12 micrograms per ml i.e. containing more than 0.06 micrograms per 0.5ml dose or where content is not stated are
	contraindicated – see Green Book and manufacturers SPC for ovalbumin content
	Postpone in any patient who has a fever at the time of vaccination appointment (minor illness without fever or systemic upset are not valid reasons to postpone immunisation)
Action if excluded	Refer to Doctor or re-schedule as appropriate
	Document in patients' clinical record reason for exclusion, advice given and action taken.
Action if patient or carer declines treatment	 Advise patients about protective effects of the vaccine and of their increased risks of influenza complications if appropriate.
decimes treatment	Advise of symptoms of flu and when to seek medical attention.
Reference to National /	 Document in patient's clinical records. Department of Health and Public Health England Letter 5 June 2013.
Local policies or	Gateway reference number: 00157. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment d
Guidelines	ata/file/207008/130613 Flu Letter v 29 Gateway GW signed.pdf Accessed <17.7.13>
	Department of Health and Public Health England Letter 26 July 2013.
	Gateway reference number: 00275. Available at:
	https://www.gov.uk/government/uploads/system/uploads/attachment_d ata/file/225360/Children_s_flu_letter_2013.pdf_Accessed <11.9.13>
	3. DOH (2006) Immunisation against Infectious Disease (The Green
	Book). Chapter 19 Influenza September 2013. https://www.gov.uk/government/uploads/system/uploads/attachment_d
	ata/file/239268/Green_Book_Chapter_19_v5_2_final.pdf Accessed <16.9.13>

2. Description of Treatment

Name, strength &	Inactivated Influenza Vaccine

formulation of drug	2013/14 Available Brands: Fluarix®, Fluarix Tetra®, Imuvac®, Agrippal®, Fluvirin®, Enzira®, Inactivated Influenza Vaccine (Split Virion) BP, CSL Inactivated Influenza Vaccine, Intanza®, Influvac Desu®, Viroflu®, Optaflu® ▼.				
	Some seasonal influenza vaccines are not licensed for use in young children – see exclusion criteria and table in Appendix 2.				
	Optaflu is the only ovalbumin free influenza vaccine				
Presentation	Suspension for injection in pre-filled syringe. Shake before use. Intanza® intradermal vaccine is supplied in a micro-needle injection system. It comes in two different formulations – Intanza® 15µg (for use in those aged 60 years and older) and Intanza® 9µg (for use in those aged 18 to under 60 years).				
Storage	Store in the original packaging in a refrigerator between +2 and +8 degrees centigrade and protected from light. Do not freeze.				
Legal Status	Prescription Only Medicine (POM)				
Black Triangle ▼	Yes Applicable to quadrivalent Fluarix Tetra and Optaflu				
Unlicensed / Off label use	No				
Route / method	Intramuscular injection into the anterolateral aspect of the thigh in young children or in the deltoid muscle of the non-dominant arm in adults and older children.				
	The deep subcutaneous route should be used for individuals with a bleeding disorder to reduce the risk of bleeding.				
	Intanza® is administered by the intradermal route (refer to manufacturers SPC for diagrams for administration).				
	Influenza vaccine can be given at the same time as other vaccines. The vaccines should be given at separate sites, preferably in a different limb. If given in the same limb, they should be given at least 2.5cm apart. Each site should be clearly specified in the patients clinical record.				
Dose	Children aged from 6 months to under 9 years in a clinical risk group who have a contraindication to the use of Fluenz® or insufficient supplies of Fluenz® – Unless specified otherwise (see note below*), a single injection of 0.5ml, repeated 4-6 weeks later if receiving an influenza vaccine for the first time ever. For those individuals who have received seasonal flu vaccine or a monovalent pandemic flu vaccine in the past, then only one dose of the influenza vaccine is required.				
	*Some seasonal influenza vaccines SPCs indicate that young children can be given either a 0.25ml or a 0.5ml dose. The Joint Committee on Vaccination and Immunisation has advised that, where these alternative doses are indicated in the SPC, a 0.5ml dose should be given to infants aged 6 months or older and young children.				
	Some seasonal influenza vaccines are not licensed for use in young children – see exclusion criteria and table in Appendix 2.				
	Children aged 9 to 17 years (both age included) in a clinical risk group who have a contraindication to the use of Fluenz® or insufficient supplies of Fluenz® - A single injection of 0.5ml for intramuscular injected vaccines.				

	Adults aged 18 to 64 (both age included) in a clinical risk group and all adults aged 65 years and over – A single injection of 0.5ml for intramuscular injected vaccines.		
	For intradermal vaccine Intanza® - a single injection of 0.1ml of Intanza® 15ug in those aged 60 years and older or 0.1ml of Intanza® 9ug in those aged 18 to under 60 years.		
Frequency of administration	See section on dose		
Duration of Treatment	See section on dose		
Supply	See section on presentation		
Total doses	Children aged over 9 years, who have a contraindication to Fluenz® or where insufficient supplies of Fluenz® exist, and adults should be given a single dose of the inactivated influenza vaccine.		
	Children aged 6 months to 9 years in a clinical risk group who have a contraindication to the use of Fluenz® or where insufficient supplies of Fluenz® exist and who have never had a dose of flu vaccination should be given two doses of the inactivated influenza vaccine at least 4 weeks apart.		
Disposal	Equipment used for immunisation, including used vials, ampoules, or partially discharged vaccines in an oral applicator, should be disposed of at the end of a session by sealing in a puncture resistant 'sharps' box, with the correct coloured lid according to local sharps and/or waste management policy and the Safe Management of Healthcare Waste (Department of Health, 2011).		
Drug Interactions ²	None reported.		
Identification & management of adverse reactions ²	Commonly reported symptoms Pain, discomfort, redness or swelling at the injection site Low grade fever, headache, malaise, fatigue, shivering, aching muscles and joint pains The above symptoms usually disappear within one to two days without treatment		
	Other adverse events Immediate reactions such as urticaria, angio-oedema and anaphylaxis can occur, most likely due to hypersensitivity to residual egg protein Neuralgia, paraesthesia, convulsions (also see note below) and transient thrombocytopenia, vasculitis without renal involvement and neurological disorders such as encephalitis have been reported very rarely over the past 30 years but no causal relationship has been established		
	The MHRA encourage prompt reporting of any cases of febrile convulsion occurring within 72 hours of receiving an influenza vaccine. It is very important that the brand name of the vaccine given, and batch number if available, are reported to the MHRA (see below). Vaccine related incidents should be reported to the NHS England Area Team via england.syb-gps.nhs.net		
Patient advice and follow up treatment	When applicable, advise patient / carer when further doses are due. Advise on management of adverse drug reactions (see section on Advice to patient		

	/ carer including written information below).		
Reporting procedure of adverse reactions	 For all influenza vaccines, report all serious suspected reactions in adults and all serious and minor reactions in children (under 18 years). Report all adverse drug reactions to the general practitioner 		
Advice to patient / carer including written information	 Advise that after immunisation, antibody levels may take up to 10-14 days to reach protective levels Discomfort, swelling, fever, aching muscles and joint pains:- usually disappear within one to two days, can treat with self-administration of paracetamol if required: Paracetamol suspension (120 mg/5ml) 6 - 24 mths 5ml 4 times per day 2 - 4 years 7.5ml 4 times per day 4 - 6 years 10ml 4 times per day 		
	Paracetamol six plus suspension (240/250 mg/5ml) 6 - 8 years 5ml 4 times per day 8 - 10 years 7.5 ml 4 times per day 10-12 years 10ml 4 times per day Over 12 years 500mg-1gram 4 times per day		
	 Monitor for fever in children for 2-3 days following immunisation if the following vaccines are used: Enzira®, CSL Inactivated Influenza Vaccine (CSL Biotherapies) or Viroflu® (these vaccines must not be given to children under 5 years due to an increased risk of fever. Ref: Green book) Other symptoms especially difficulty with breathing, unsteadiness or weakness, swelling: Seek medical advice urgently If general symptoms persist seek medical advice. 		
Special considerations and additional information	Minor illness, without fever or systemic upset, is not a valid reason to postpone 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 signs or symptoms to adverse effects of the vaccine.		
	As with most vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.		
	Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection and access to a telephone.		

In all cases manual records in line with NMC Record Keeping Guidance Records (2009) and other professional codes of practice must be maintained, including the Personal Held Child Record (PHCR – red book), GP records, computerised records and data collection for Child Health Information Services (CHIS) should include: Assessment of the patient's need in relation to the intervention Patient's name, address, date of birth and GP with whom the patient is registered. Diagnosis Dose and form of vaccine supplied Quantity supplied Brand, batch number and expiry date of vaccine Date given Name of the practitioner administering the vaccine Consent – following local guidelines

Advice given to the patient/carer
Advice given if excluded or declines treatment
Record how the patient's central record or GP surgery record will be updated
Details of any adverse drug reactions and actions taken
Record supplied via PGD
Entries made in any record should ensure the practitioner delivering the care is clearly identifiable. Clinical records must be kept for at least 8 years following completion of treatment. In patients aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death.
A record of vaccination must, where given by a provider other than the patients registered GP or P/N be provided to the patients registered GP/practice within one working day.

3. Characteristics of Staff

Qualifications required	Desistant Name and the state of		
Qualifications required	Registered Nurse currently registered with the NMC or other registered		
	health professional commissioned by NHS England and who has completed		
	a relevant immunisation training programme		
Additional requirements	Training and competence in all aspects of immunisation including		
_	contraindications and the recognition and treatment of anaphylaxis.		
	Awareness of employing organisations' policy on the management of		
	anaphylaxis.		
1	Immediate access to Adrenaline/Epinephrine 1:1000 (1mg/ml)		
	Knowledge of and access to;		
	Accompanying product information leaflet/Summary of Product		
	Characteristics (SPCs)		
	 NMC (2009) Record Keeping Guidance 		
	o NMC (2008) The Code		
	NMC (2010) Standards for Medicines Management		
	Relevant professional code of practice		
	o DOH (2006) Immunisation against infectious disease (<i>The Green Book</i>),		
	relevant updates and compliance with its recommendations (now only		
	available electronically)		
	CCG or individual organisations' Consent Policy		
	Roles and responsibilities when working under a PGD (NICE guidelines,		
	2013)		
Continued training			
requirements	and the state of apaciting with cylicoloc of continued i		
	professional development as appropriate and in line with PREP (Post		
	Registration Education and Practice) or other registration requirements.		
İ	 Training and competence in all aspects of vaccination and immunisation 		
	including contraindications and the recognition, management and		
	treatment of anaphylaxis.		
	o Annual updates on resuscitation skills (including defibrillation training)		
	and the management of anaphylaxis within the community.		

7

4. PGD Development

Developed & Produced by:	Name	Signature	Date
Senior Pharmacist	Caron Applebee	Applee	18.9.13
Doctor (Lead Author)	Dr Nachi Arunachalam	Ar Dadniappour	18.9.13
Registered Nurse	Kathy Wakefield	Kawa Cepen I	18.9.13

Acknowledgements

Name	Designation

5. Organisational Authorisations

The PGD is not legally valid until it has had the relevant organizational authorization.

It is the responsibility of the organization that has legal authority to authorize the PGD, to ensure that all legal and governance requirements are met.

Complete details below or use format agreed according to local policy.

Approved by:	Name	Signature	Date
Local Clinical Governance Committee e.g. DTC/MMT	Dr David Black Medical Director NHS England, South Yorkshire & Bassetlaw Area Team	Paul Har	17.9.13
Additional signatories according to local policy e.g. independent contractor providers.	Mrs Margaret Kitching, Director of Nursing & Quality NHS England, South Yorkshire & Bassetlaw Area Team	M Kitch	18.9.13

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 or an individual agreement according to local policy.

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 xxx (insert name Care Professional who has signed the PGD	e of organisation) for the named Health
Signed	Date
Name (Print)	
Designation	

Note to Authorising Manager

By signing about 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 1: Clinical Risk Groups

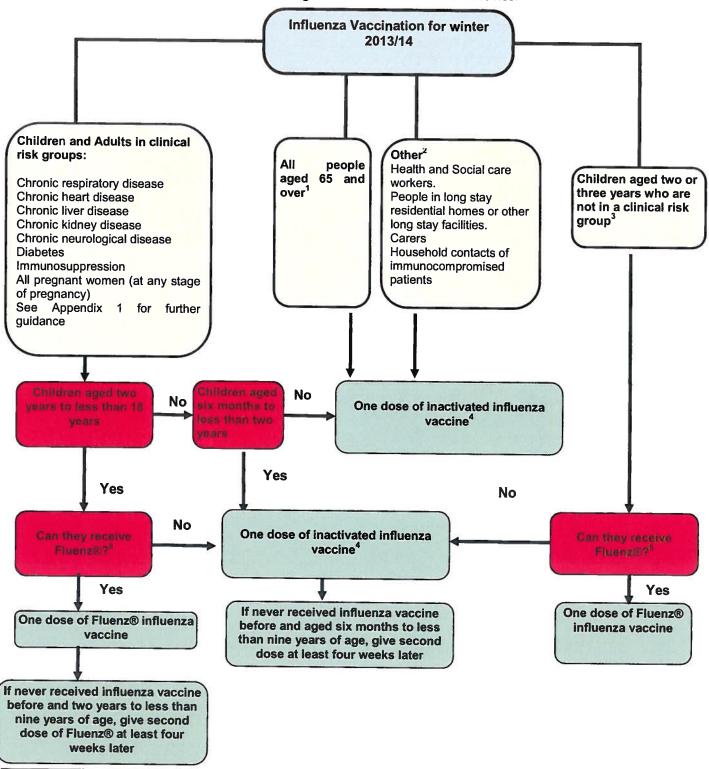
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	It is difficult to define at what level of immunosupression, a patient could be considered to be at a greater risk of the serious consequences of flu and should be offered flu vaccination. This decision is best made on an individual basis and left to the patient's clinician.
	Some immunocompromised patients may have a suboptimal immunological response to the vaccine.
	Consideration should also be given to the vaccination of household contacts of immunocompromised individuals, i.e. individuals who expect to share living accommodation on most days over the winter and therefore for whom continuing close contact is unavoidable. This may include carers
Pregnant women	Pregnant women at any stage of pregnancy (first, second or third trimester)

The list above is not exhaustive and the medical 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. Trivalent seasonal flu vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above.

Appendix 2: Chart summarising the advice on influenza vaccination for the 2013/14 influenza vaccination programme. The chart should be read in conjunction with the information within this PGD and also Appendix 3 which gives details about the age indications for influenza vaccines.



- 1. all those aged 65 years or older including all those aged 65 years on or before 1 March 2014
- 2. follow additional guidance from UK health departments
- all children aged two or three years (but not four years or older) on or before 1 Sept 2013
- 4. if quadrivalent inactivated vaccine available, consider for children age three years and older only. If quadrivalent unavailable, offer suitable trivalent inactivated influenza vaccine. See Appendix 3 which lists the vaccines that can be used in young children some are not suitable for young children
- cannot receive if: under age of two years; 18 years and older; have severe asthma (BTS SIGN step 4 or above); active
 wheezing at time of vaccination; egg allergy; certain immunodeficiencies; or pregnant see contraindications and
 precautions for full list.
- 6. Fluenz® is the vaccination of choice for children aged 2 years to 17 years where sufficient supplies exist. If Fluenz® is in short supply then it is acceptable to use an inactivated influenza vaccine suitable for the patients age (see Appendix 3)

Appendix 3: Seasonal Influenza Vaccines for the 2013/14 Influenza Season

Supplier	Name of product	Vaccine type	Age indications	Ovalbumin content per dose
A. I 14 I 14	Influvac Desu®	Trivalent Surface antigen, inactivated	From 6 months	No more than 0.1µg per 0.5ml dose
Abbott Healthcare	lmuvac®	Trivalent Surface antigen, inactivated	From 6 months	No more than 0.1µg per 0.5ml dose
AstraZeneca UK Ltd	FLUENZ®	Trivalent Live attenuated, nasal	From 24 months to less than 18 years of age	No more than 0.24µg per 0.2ml dose
GlaxoSmithKline	Fluarix®	Trivalent Split virion inactivated virus	From 6 months	No more than 0.05µg per 0.5ml dose
	Fluarix Tetra®	Quadrivalent Split virion inactivated virus	From 3 years	No more than 0.05µg per 0.5ml dose
Janssen-Cilag Ltd (formerly Crucell UK Ltd)	Viroflu®	Trivalent Surface antigen, inactivated	From 6 months (Before use in children aged under five years, consult adverse reactions section)	No more than 0.05µg per 0.5ml dose
MASTA	Inactivated Influenza Vaccine (Split Virion) BP	Trivalent Split virion inactivated virus	From 6 months	No more than 0.05µg per 0.5ml dose
	Fluarix®	Trivalent Split virion inactivated virus	From 6 months	No more than 0.05µg per 0.5ml dose
	Imuvac®	Trivalent Surface antigen, inactivated	From 6 months	No more than 0.1µg per 0.5ml dose
Novartis Vaccines	Agrippal®	Trivalent Surface antigen, inactivated	From 6 months	No more than 0.2µg per 0.5ml dose
	Fluvirin®	Trivalent Surface antigen, inactivated	From 4 years	No more than 1µg per 0.5ml dose
	Optaflu®	Trivalent Surface antigen, inactivated, prepared in cell culture	From 18 years	No Ovalbumin
Pfizer Vaccines	Inactivated Influenza Vaccine	Trivalent Split virion inactivated virus	From 5 years (Before use in children aged under nine years, consult adverse reactions section)	No more than 1µg per 0.5ml dose
	Enzira®	Trivalent Split virion inactivated virus	From 5 years (Before use in children aged under nine years, consult adverse reactions section)	No more than 1µg per 0.5ml dose
Sanofi Pasteur MSD	Inactivated Influenza Vaccine (Split Virion) BP	Trivalent Split virion inactivated virus	From 6 months	No more than 0.05µg per 0.5ml dose
	Intanza® 9µg	Trivalent Split virion inactivated virus	From 18-59 years	No more than 0.024µg per 0.1ml dose
	Intanza® 15µg	Trivalent Split virion inactivated virus	From 60 years	No more than 0.024µg per 0.1ml dose