This document expires on 12/12/2014
Patient Group Direction Number VI 26

Patient Group Direction (PGD) for

The Administration of the Seasonal Influenza (Intanza®▼) Vaccine to Target Risk Group Patients by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

PGD Number:	VI 26
Author:	Kathy Wakefield, Lisa Murray.
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1. Clinical Condition

Seasonal Influenza Vaccine Tri-valent (Intanza®▼)

Clinical Indications	Immunisation against Influenza in accordance with the current National Seasonal Influenza Immunisation Programme. **NB.** Please note this is not the first line vaccine-only to be used in times of supply problems.
Criteria for inclusion	• Valid, legal consent obtained and check-list completed. • All patients aged 65 and over. • Pregnancy-at any stage of pregnancy. • Adults from 18 years with: ▪ Chronic heart disease ▪ Chronic respiratory disease and asthmatics requiring continuous or repeated use of inhaled or systemic corticosteroids or with previous exacerbations requiring hospital admission ▪ Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation. ▪ Chronic liver disease (including cirrhosis) ▪ Diabetes mellitus (Type I and II) ▪ Multiple sclerosis and related conditions ▪ Chronic neurological disease eg stroke/TIA. Conditions in which respiratory function may be compromised eg polio syndrome sufferers. Cerebral palsy, hereditary and degenerative diseases of the CNS/muscles; or severe neurological disability. • Those living in long-stay residential and nursing homes, where rapid spread of influenza is likely to follow introduction of infection and cause high morbidity and mortality. • Immunosuppression due to disease or treatment, including asplenia or splenic dysfunction. HIV at all stages; patients undergoing chemotherapy leading to immunosuppression; • Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone 20mg or more per day (any age) or for children under 20kgs a dose of 1mg prednisolone or more per kg per day. • People who are in receipt of a carer's allowance or who are the main carer for an elderly or disabled person whose welfare may be at risk if the carer falls ill. • Healthcare workers directly involved in patient care. Note: if not included in the above but considered to be at risk further advice

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	should be sought from the GP & recorded as having been sought before administration.
Criteria for exclusion	• No valid, legal consent given. • Current acute febrile illness. • Anaphylactic hypersensitivity to egg, egg products, gentamicin, polymyxin. Such patients should be referred to the planned investigation unit as per seasonal flu plan. • Previous significant or serious local or systemic reaction to influenza vaccination. • Children under 18 years of age. • Adults over 18 years old who are not considered as being at high risk of serious illness should they develop influenza. • Those living in long stay care facilities such as prisons, young offender institutions, university halls of residence etc.
Action if excluded	• If excluded because of valid legal consent, obtain legal consent. • For acute febrile illness advise when vaccine may be given. • Specialist advice must be sought on the vaccines and circumstances under which they should be given. The risk to the individual of not being immunised must be taken into account. • Arrange for further appointment if needed. • Document all discussions and explanations re: risk of vaccination and not receiving vaccination in patient's clinical record. • Notify Child Health for under 19s that vaccination not given and reason why.
Action if Patient/ Parent/Legal Guardian declines Treatment	• Advise patient of the potential risks if they should develop influenza. • Advise with regard to flu symptom management – rest, fluids and OTC remedies. • Inform GP. • Record in patient's clinical notes.
Drug Interactions	Some patients on warfarin, theophylline or phenytoin may occasionally experience an enhancement of their effects with influenza vaccine. The benefits of immunisation will outweigh the effects of the interaction. **Note:** in case of doubt, further advice should be sought from the GP and recorded as having been sought before administering the drug and from individual Summary of Product Characteristics (SPC) for compatibility of products.

2. The Vaccine

Seasonal Influenza Vaccine (Tri-valent- 'Intanza'®▼)

Name, strength and formulation of drug	• Intanza ▼ 15 microgram/strain suspension for injection in a micro-needle injection system • Intanza ▼ 9 microgram/strain suspension for injection for injection in a micro-needle injection system

Legal status	• POM (Prescription Only Medicine) • Black triangle ▼-intensively monitored by CHM and MHRA.
Storage	Vaccines must be stored, transported and disposed according to manufacturers and the Department of Health guidelines and current legislation.
Dose	• **Adults aged between 18 years and 59 years**-A single injection of 0.1ml Intanza®▼ 9mcg • **Adults aged over 60 years-** A single injection of 0.1ml Intanza®▼ 15mcg
Route/ method	• **Intra-dermal**-this route differs from all the other seasonal 'flu vaccine brands. Please refer to the product leaflet contained within the packaging for details. • Preferred site for adults–deltoid muscle. • Allow vaccine to reach room temperature before use.
Frequency of Administration	• Annual dose.
Total dose number	• One
Patient/carer advice and follow-up treatment	• Inform individual about possible side effects and their management. • Give advice on temperature control *only* if patient become feverish. Whilst paracetamol and ibuprofen can lower the duration of fever and reduce distress, there is no evidence that they prevent febrile convulsions. It is not therefore recommended that these drugs are used routinely to prevent fever following vaccination as there is some evidence that prophylactic administration of antipyretic drugs around the time of vaccination may lower antibody responses to some vaccines. • Give advice regarding normal reaction to the injection. • Inform patient when subsequent doses are due when applicable. • Please include a copy of any patient information to be given with this medicine. (Provision of the Package Leaflet is a legal requirement). • Local reactions (pain, erythema, induration and oedema) within 48 hours after vaccination, and persisting for 1-2 days. • Advise on need for revaccination if needed • Information about signs symptoms of disease. **Following immunisation/vaccination:** • The patient should be observed for an immediate adverse reaction, usually 10 minutes and should remain under observation until they have been seen to be in good health and not to be experiencing an immediate adverse reaction.

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3. Records

1. **The following records should be kept either paper or computer based records should be kept at GP practice / Child Health / Patient (Parent) Held Record / Nursing Record/Pharmacy as appropriate**
   - Complete Record of Attendance documentation and if appropriate enter on record 'Protocol fulfilled'
   - Patient's name, address, date of birth and consent given
   - Diagnosis
   - Name of medication including strength.
   - Dose given.
   - Batch Number and Expiry Date (if supplied)
   - Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment
   - Route and site of administration (record all sites of administration to allow any reactions to be related to the site of the injection
   - Contact details of GP (if registered)
   - Advice given to patient (including side effects)
   - Details of any adverse drug reaction and actions taken including documentation in the patient's medical record
   - Referral arrangements (including self care)
   - Date administered / supplied
2. **Vaccine Audit Trail Data Collection**
   - **Reconciliation**: Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient by patient basis
   - **Storage**: Standards must be consistent with the Summary of Product Characteristics. All medication must be stored in a secure locked environment away from the direct patient care area

4. Anaphylaxis - Emergency Treatment

Before administering any medication the possibility of anaphylaxis must be discussed and documented with the patient/carer prior to administration of any medication, which may produce an anaphylactic reaction.
When giving any medication the following should always be readily available:

- Access to the patients notes
- Adrenaline (Epinephrine) 1 in 1000 for intramuscular (i.m.) injection for use in emergency (NB: **check expiry dates** regularly)
- Syringes and needles of **suitable size** and capacity for dose.
- Patient Group Direction for the Administration of Adrenaline (Epinephrine) 1 in 1000.
- Access to a telephone

PLEASE BE AWARE OF CURRENT RESUSCITATION COUNCIL GUIDELINES.

Adrenaline (Epinephrine) 1 in1000 (1mg/ml)	**For intramuscular injection**	
Age	Dose	Volume
Children under 6 years	150 micrograms	0.15ml
Children 6 – 12 years	300 micrograms	0.3ml
Adults and child 12-18 years	500 micrograms	0.5ml
These doses may be repeated if necessary at 5-minute intervals according to blood pressure, pulse and respiratory function.		
Special cautions: see BNF 3.4.3	Epinephrine/ Adrenaline	

BNF 64 section 3.4.3 p.202-205 (Updated Jan 2008)

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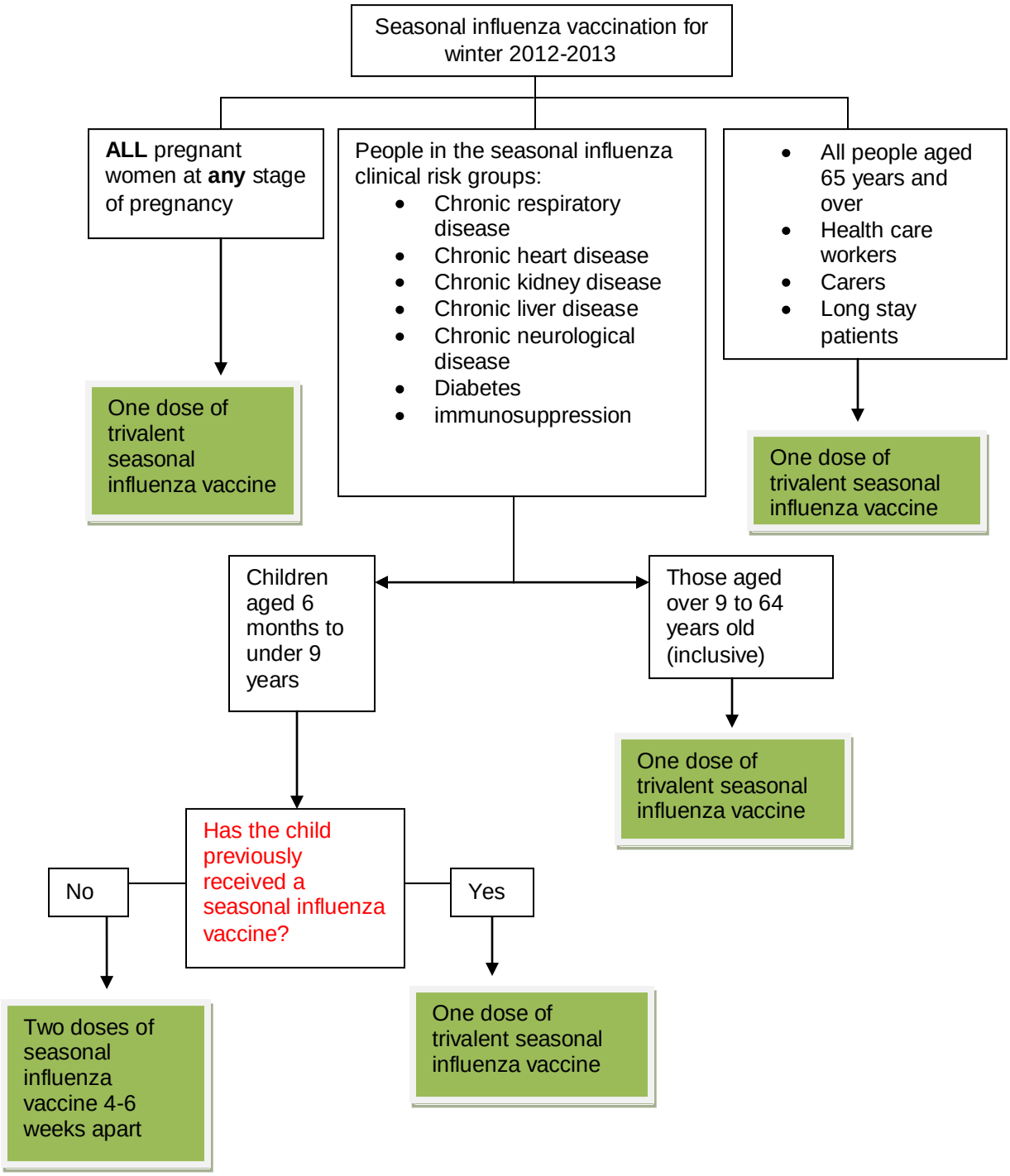
Appendix 1: Seasonal Influenza Vaccination Programme for winter 2012-2013.



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5. Professional Responsibility - All practitioners

- The practitioner will ensure he/she has the relevant training and is competent, including contra-indications. He/she will attend training updates as appropriate. Details of the competency programme developed for use with this PGD must be attached (see PGD process above).
- The practitioner will have due regard for their Professional Conduct and Guidelines for the Administration of Medicines
- It is the responsibility of the individual practitioner to ensure that he/she has appropriate knowledge of the product prior to proceeding. Refer to the Summary of Product Characteristics (SPC) or current BNF for further details on the product.
- Must have access to a current copy of the BNF and *Immunisation against infectious disease* ('Green book') and comply with its recommendations (available on DH website – www.dh.gov.uk/greenbook)
- Each individual must have received a personal copy of the PGD and signed on the list of individual professionals who may work within this PGD (kept with master copy of this PGD)
- Must be competent in the recognition and management of anaphylaxis.
- Must have access to all relevant DH advice, including the relevant CMO letters or training and competent in all aspects of immunisation including contraindications and recognition and treatment of anaphylaxis.
- Annual attendance at NHS Rotherham's or workplace update on resuscitation skills and the management of anaphylaxis within the community.
- Regular updates in immunisation, vaccination, anaphylaxis and cardiopulmonary resuscitation
- To reinforce and update knowledge and skills in this area of practice, including basic resuscitation and anaphylaxis training, with particular reference to changes and national directives.
- Maintenance of own level of updating with evidence of continued professional development (PREP requirements)
- Such practitioners that meet the above criteria for training have NHS Rotherham approval to administer Influenza vaccine in accordance with this PGD without a doctor's prescription, and with the patient's informed consent.

Sources:

- HSC 200/026 Patient Group Directions;
- Refer to NHS Rotherham Procedure N1 Procedure for Emergency Treatment of Anaphylactic Reactions in the Community (link http://websrv.rotherhampct.nhs.uk/?FileID=9575)
- Department of Health (2006-web version only): Immunisation against infectious disease. The 'Green book' chapter 19 – Influenza www.dh.gov.uk/greenbook.
- www.immunisation.nhs.uk
- Current edition of BNF www.bnf.org.uk
- Summary Product Characteristics available http://www.medicines.org.uk.
- NMC 2007 Standards for Medicine Management.
- NMC Code of Professional Conduct (2008).
- Resuscitation Council (UK) Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses www.resus.org.uk/siteindx.htm.
- Patient Group Direction' National Prescribing Centre 2004 www.npc.co.uk/publications/pgd.pdf.

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6. Management of patient group direction

This patient group direction is to be read, agreed to and signed by all health professionals to whom it applies. One copy should be given to each nurse with the original signed with a copy being kept by the nominated doctor with responsibility for PGDs within the organisation.

Adapted from DH template

Developed by:-	**Name & Title** *in block capitals*	***Signature***	***Date***
Advice sought from	*SUZANNA MATTHEW*		
Lead pharmacist	*LISA MURRAY*		
Health Protection and Infection Prevention Manager	*KATHY WAKEFIELD*		

The Administration of the Seasonal Influenza Vaccine (Tri-valent-Intanza®▼) to Target Risk Group Patients by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.			
This Patient Group Direction for use in NHS Rotherham is authorised by us			
Job Title	**Name**	**Signed**	**Date**
Director of Public Health	*Dr John Radford*		
Medical Director	*Dr David Plews*		
Head of Medicines Management	*Stuart Lakin*		
Senior Partner (or delegate) - for GP employed nurses only			

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The registered nurses named below, being employees of

NHS Rotherham based at…….……..*Clinic

OR GP Employer Name* ……..……..
***delete/complete as appropriate**

are authorised to administer Seasonal Influenza vaccine as specified under this Patient Group Direction

Register of Staff trained and assessed to administer this vaccine: (additional sheets may be attached)

"I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct".

Name of authorised practitioner	Signature of authorised practitioner	Clinical manager or GP	Signature of clinical manager or GP	Date

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