Patient Group Direction (PGD) for

The Administration of Combined low-dose Diphtheria, Tetanus, and Inactivated Polio Vaccine (Revaxis®) to individuals aged over 10 years, by Registered Nurses employed or commissioned by NHS Rotherham CCG who have been certified after completing an agreed training plan.

PGD Number:	VI 7
Author:	Kathy Wakefield/Lisa Murray
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Dissemination:	General Practices & TRFT
Implementation:	Relevant Clinical Lead
File Location:	Prescribing & Medicines Management with link to policies and procedures
Key Words:	Combined Diphtheria (low dose), Tetanus, Inactivated Polio Vaccine (Td/IPV-Revaxis®), Patient Group Directions, Vaccination.
Date Uploaded & By Whom:	

Patient Group Directions are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

- Each PGD has a unique identifier allocated by the Prescribing Adviser responsible for the management of Patient Group Directions for the organisation.
- Once a PGD has been given approval, the date on which the PGD comes into effect will be inserted by the Prescribing Adviser prior to submission onto the NHS Rotherham CCG intranet.
- The PGD must be reviewed within two years of authorisation
- PGDs that have failed to be reviewed and re-ratified ***must not*** be used past their expiry date and patient specific direction (prescriptions) must be used to authorise supply of medicines.

The Administration of Combined low-dose Diphtheria, Tetanus, and Inactivated Polio Vaccine (Revaxis®) to individuals aged from 10 years, Registered Nurses employed or commissioned by NHS Rotherham CCG who have been certified after completing an agreed training plan.

1. Clinical Condition or situation to which the direction applies

Drug Name: Combined low-dose diphtheria, Tetanus, and Inactivated Polio Vaccine (Td/IPV - *Revaxis*®)

Clinical Indications	For active immunisation against diphtheria, tetanus and polio in individuals aged from 10 years of age: • A booster vaccination against diphtheria, tetanus and poliomyelitis. • **As a primary course in previously unimmunised individuals or where there is an unreliable history of previous immunisation against diphtheria, tetanus and poliomyelitis*.** • To complete a primary course of immunisation against diphtheria, tetanus or poliomyelitis*. *These recommendations are “off-licence”, but are in line with recommendations of JCVI as contained in revised chapters for the book Immunisation against Infectious Disease ’The Green Book’

Criteria for Inclusion	Any child aged 10 years and over or adult where:- • Valid, legal consent has been given to receive the vaccine. • There is either no history or an incomplete history of a primary course of diphtheria, tetanus, poliomyelitis. • A booster is required following a primary course of immunisation of diphtheria, tetanus and poliomyelitis.
Criteria for Exclusion	• No valid, legal consent. • Children under 10 years. • Any individual who has had an anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis and inactivated polio-containing vaccine or an anaphylactic reaction to neomycin, streptomycin or polymixin B (which may be present in trace amounts) • Fever or current acute febrile systemic illness. In this case vaccination should be postponed until the patient has recovered. Minor infections, without fever or systemic upset are not reasons to postpone vaccination. • Neurological complications following and earlier immunisation against diphtheria and /or tetanus. • Hypersensitivity to any component of the vaccine. • Individuals who have completed a primary vaccination course of a vaccine containing diphtheria or tetanus toxoids within the previous 12 months.
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. • Document in patient's clinical record. • Arrange for further appointment if needed. • Notify Child Health. • Inform the relevant Health Visiting Team.

Action if Parent/Legal Guardian declines Treatment	• Advise about the protective effects of the vaccine and the risks of infection and disease complications. • Inform or refer to Medical Practitioner. • Document action and advice given in patients clinical record. • Notify Child Health.
Notes for doctors / drug interactions	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. 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. Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be considered for diphtheria-containing vaccines in accordance with the recommendations above. However, these individuals may not develop a full antibody response if they are immunosuppressed, and vaccine protective efficacy has not been studied. Re-immunisation should be considered after treatment is finished and recovery has occurred. Specialist advice may be required.

2. Description of treatment

Drug Name: Adsorbed Diphtheria (low dose), Tetanus and Inactivated Poliomyelitis vaccine (Brand Revaxis®)

Name, strength and formulation of drug	Adsorbed low dose Diphtheria, Tetanus, and Inactivated Polio vaccine (Td/IPV - *Revaxis*®) is in the form of a sterile liquid suspension (cloudy white appearance) supplied in a single 0.5ml pre-filled syringe.
Legal status	POM - Prescription only medicine.
Storage	Vaccines must be stored, transported and disposed according to manufacturers and the Department of Health guidelines and current legislation.
Dose/dose range	0.5ml
Method /route	***N.B. Shake vaccine well immediately before administration*** *Revaxis*® is routinely given by intramuscular injection. **Bleeding disorders**-administration must be by deep subcutaneous injection.

	The site at which the vaccine was given should be noted in the individual's records.
Frequency of administration	• A primary course of three doses administered at one month intervals in previously unimmunised individuals (aged over 10 years old) or where there is no history of a primary course of diphtheria, tetanus and polio vaccination. • To complete a course where there is an incomplete history of a primary course of diphtheria, tetanus and polio vaccination (see indications). • A single booster dose should be administered to previously immunised children aged over 10 years of age and adults: ▪ 3 years after the primary course (this interval can be reduced to 1 year if the course was delayed) ▪ 10 years after the first booster dose (this interval can be reduced to 5 years if the previous doses were delayed) ▪ Travel to areas with a risk of diphtheria infection should receive a further booster dose if more than 10 years has elapsed since completion of the UK vaccination schedule
Total dose number	**Primary course-** 3 doses. **To complete primary course-** Variable according to number of previous primary doses received. **Booster doses**- 2 doses. All individuals should receive a total of 5 doses of diphtheria, tetanus and polio-containing vaccines to ensure long-term protection through adulthood.
Patient/carer advice and follow-up treatment	• Inform individual about possible side effects and their management. • Give advice on temperature control if they become feverish. • 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. • Inform Child Health Department that vaccination has been given. **Following immunisation/vaccination:** The patient should be observed for an immediate adverse reaction, usually 5-10 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.

3. Records

1. The following records should be kept either paper or computer based
   For all vaccinations, the following information should be entered on all manual records including the Personal Child Health Record (PCHR-red book), computerised records and data collection for Child Health Information Services (CHIS):

   Records should be kept at ……. and information passed to patient and GP.

   - 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
   - Dose given.
   - Brand, 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)
   - Information & advice given to patient (including side effects)
   - Details of any adverse drug reaction and actions taken, including documentation in the patient's medical record. Any adverse reaction must be notified to GP.
   - Referral arrangements (including self care)
   - Date administered / supplied
   - Any serious adverse events that may be attributable to black triangled drugs ▼ should be reported via SUI trust procedure and then to the MHRA using the yellow card system.
2. **Audit Trail Data Collection**

- A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each practice/service.

- **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 RESUSCITATION COUNCIL GUIDELINE.

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 Adolescents 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 (61st edition) section 3.4.3 page 197-199

(Updated Jan 2008)

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 the their Professional Conduct and Guidelines for the Administration / Supply 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.
- 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 o*r* training and competent in all aspects of immunisation including contraindications and recognition and treatment of anaphylaxis where appropriate.
- Must have access to a current copy of the BNF and *Immunisation against infectious disease* (The 'Green book') and comply with its recommendations (available on DH website – www.dh.gov.uk/greenbook) where appropriate.
- Annual attendance at the NHS Rotherham's or workplace update on resuscitation skills and the management of anaphylaxis within the community.
- Maintenance of own level of updating with evidence of continued professional development (PREP requirements).
- Regular updates in immunisation, vaccination, anaphylaxis and cardiopulmonary resuscitation where appropriate.
- 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.
- Such practitioners that meet the above criteria for training have NHS Rotherham approval to administer/supply Adsorbed Diphtheria (low dose), Tetanus and Inactivated Poliomyelitis vaccine (Revaxis®) in accordance with this PGD without a doctor's prescription, and with the patient's informed consent.
- Storage and handling of medicines should be carried out accordance with NHS Rotherham's Medicines Policy.
- The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicine, including those supplied under Patient Group Directions and all products other than those immediately administered must be labelled for supply to patients.

Sources: HSC 200/026 Patient Group Directions; BNF 64th Edition (Sept. 2012); Current Summary of Product Characteristics for product.
Refer to NHS Rotherham Procedure N1 Procedure for Emergency Treatment of Anaphylactic Reactions in the **Community (link http://websrv.rotherhampct.nhs.uk/?FileID=9575) UK Resuscitation Council (January 2008)**

Other reference sources.

5. Management of Patient Group Direction

Developed by:-	Name & Title	Signature	Date
Prepared and approved by: *Name and title in block capitals*			
Advice sought from	*Suzanna Mathews*		
Lead pharmacist	*Lisa Murray*		
Lead health professional from group who will administer/supply medicine *e.g. Sister XXXX Diabetic Nurse Specialist*	*Margaret Murphy*		
Health Protection and Infection Prevention Manager	Kathy Wakefield		

Supply / Administration of Combined low-dose Diphtheria, Tetanus, and Inactivated Polio Vaccine (Revaxis®) by Registered Nurses employed or contracted by NHS Rotherham CCG working within GP Practices registered in 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*		
NHS Rotherham CCG Prescribing Lead	*Dr. Jason Page*		
Head of Medicines Management	*Stuart Lakin*		
Senior Partner (or delegate) - for GP employed nurses only			

The registered nurses named below, being employees or contractee's of

NHS Rotherham CCG based at…….*Clinic

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

are authorised to administer/supply Diphtheria, Tetanus, and Inactivated Polio Vaccine (Revaxis®) as specified under this Patient Group Direction

Register of Staff Trained and Assessed to Administer or Supply this Medicine:
(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