Patient Group Direction (PGD) for

The Administration of Combined low-dose diphtheria, Tetanus, acellular Pertussis and Inactivated Polio Vaccine (dTaP/IPV- REPEVAX®) by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

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Author:	Kathy Wakefield and Lisa Murray
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Key Words:	Combined diphtheria (low dose), Tetanus, acellular Pertussis and Inactivated Polio Vaccine, (dTaP/IPV-Repevax®), Patient Group Directions, Vaccination.
Date Uploaded & By Whom:	Becky Stevens

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 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.

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1. Clinical Condition or situation to which the direction applies

Drug Name: Combined low-dose diphtheria, Tetanus, acellular Pertussis and Inactivated Polio Vaccine (dTaP/IPV - REPEVAX®)

Clinical Indications	• A booster vaccination against diphtheria, tetanus, pertussis and poliomyelitis in children aged from 3 years 4 months to under 10 years of age. • As part of the temporary vaccination programme of pregnant women against pertussis infection.

Criteria for Inclusion	• Any child aged from 3 years 4 months to under 10 years of age where:- Parent/guardian consent has been given to receive the vaccine. A primary course of 3 doses of diphtheria, tetanus, pertussis and polio vaccines has previously been given. The vaccines can have been DTP-Hib & IPV, DTaP-Hib & IPV or DTaP/Hib/IPV. • Any pregnant woman (between 28 weeks up to onset of labour). NB. Use in pregnancy is 'off-license' but recommended by the Joint Committee for Vaccination and Immunisation (JCVI). • Vacccination may be offered to new mothers regardless of having previously been vaccinated against pertussis (unless vaccinated in this pregnancy), up to when their child receives their first vaccination.
Criteria for Exclusion	• No valid legal consent • Children 10 years or older • Women less than 28 weeks pregnant • 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). • Children who have completed a primary vaccination course of a vaccine containing diphtheria or tetanus toxoids within the previous 12 months. • 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. • Any individual who experienced an encephalopathy of unknown origin within 7 days of previous immunisation with a pertussis-containing vaccine • Neurological complications following an earlier immunisation against diphtheria and /or tetanus. • Hypersensitivity to any component of the vaccine.

	• Pregnancy/new mothers if less than one month since immunisation with pertussis/diphtheria/tetanus and/or polio. • Pregnancy/new mothers if already vaccinated in the current pregnancy under the temporary vaccination programme. REPEVAX® is not recommended for primary immunisation in children under 10 years of age with an incomplete or no history of a primary course of diphtheria, tetanus toxoid or polio vaccine because it only contains low dose diphtheria.
Action if Excluded	• 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. • Notify Child Health. • Record in patient's record
Action if Patient declines Treatment	• Advise about the protective effects of the vaccine (including the transfer of proective antibodies to the unborn child-offering protection until they can be vaccinated at 2 months of age) and the risks of infection and disease complications. • Inform or refer to Medical Practitioner. • Document action and advice given in patients clinical record. • Inform Health Visitor and School Nurse if appropriate. • If patient is pregnant woman ensure their midwife is informed and hand-held records updated.
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: Combined low-dose diphtheria, Tetanus, acellular Pertussis and Inactivated Polio Vaccine (dTaP/IPV - REPEVAX®)

Name, strength and formulation of drug	Adsorbed low dose diphtheria, tetanus, acellular pertussis and Inactivated Polio Viruses vaccine (dTaPIPV - REPEVAX®) is in the form of a sterile liquid suspension supplied in a single dose (0.5 ml) prefilled syringe with an elastomer stopper.
Legal status	POM
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 – maximum dose 0.5 ml
Method /route	REPEVAX® is routinely given by intramuscular injection to the deltoid. Vaccination by deep subcutaneous route should be reserved ***only*** for individuals with a bleeding disorder.
Frequency of administration	• A single booster dose should be administered for children aged between 3 years and 4 months and 9 years inclusive. If the primary vaccination course was delayed this booster dose may be given at the scheduled time-provided it is one year since the third primary dose. If a person attends for a routine booster dose and has a history of receiving a vaccine following a tetanus-prone wound, attempts should be made to identify which vaccine was given. If the vaccine given at the time of the injury was the same as that due at the current visit and was given after an appropriate interval, then the routine booster dose is not required. Otherwise, the dose given at the time of injury should be discounted as it may not provide long-term protection against all antigens, and the scheduled immunisation should be given.

	• Pregnancy-A single dose of Repevax® is recommended. • New mothers-A single dose of Repevax® is recommended unless vaccinated during the most recent pregnancy under the temporary vaccination programme.
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 Patient Information Leaflet is a legal requirement). • Local reactions (pain, erythema, induration and oedema) within 48 hours after vaccination, and persisting for 1-2 days. **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.
Reporting procedure of adverse reactions	• Any serious adverse reaction to the vaccine should be documented in their medical records and GP informed. • Any adverse events that may be attributable to Repevax vaccination should be reported to the MHRA using the yellow card system. www.yellowcard.gov.uk and Sanofi Pasteur MSD Limited, the pharmaceutical company that manufactures *Repevax*®, on 01628 587 693 • Local incident reporting procedures must be followed.

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–Jan 2008.

Adrenaline (Epinephrine) 1 in1000 (1mg/ml)	**For intramuscular injection**	
Age	Dose	Volume
Children under 6 years	150 micrograms	0.15ml
Children 6 – 11 years (Inclusive)	300 micrograms	0.3ml
Adults and child over 12 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 (63rd edition) section 3.4.3 page 205-208

(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 Combined low-dose diphtheria, Tetanus, acellular Pertussis and Inactivated Polio Vaccine (dTaP/IPV-REPEVAX®) 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 63rd Edition (Mar 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*			
Lead doctor/dentist			
Health Protection and Infection Prevention Manager	Kathy Wakefield		
Lead pharmacist	*Lisa Murray*		
Lead health professional from group who will administer/supply medicine *e.g. Sister XXXX Diabetic Nurse Specialist*	*MARGARET MURPHY*		

Supply / Administration of Adsorbed Diphtheria, Tetanus, Pertussis, (Acellular Component) and Inactivated Poliomyelitis Vaccine (Repevax®) by Registered Nurses employed or contracted by NHS Rotherham 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*		
Medical Director	*Dr. David Plews*		
Head of Medicines Management	*Stuart Lakin*		
TRFT Chief of Community Service	*Andy Irvine*		
Senior Partner (or delegate) - for GP employed nurses only			

The …… named below, being employees or contractee's of

NHS Rotherham based at…….*Clinic

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

are authorised to administer/supply ……..
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