

PATIENT GROUP DIRECTION

Administration of Combined Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio and Haemophilus influenzae type b vaccine DTaP/IPV/Hib Primary Immunisation to Children aged 2 months to 10 years by Registered Nurses to patients registered with General Practitioners within NHS Cambridgeshire

Issue date: 1st December 2011

Supersedes: PGD Administration of Combined Diphtheria, Tetanus, acellular Pertussis, inactivated Polio and Haemophilus influenzae type b vaccine DTaP/IPV/Hib Primary Immunisation to Children aged 2 months to 10 years (expired November 2011)

Expiry date: 30th November 2013, or earlier in the light of local or national changes

Developed & produced by:

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June Grainger	Practice Nurse	Signed on	29.11.2011
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This patient group direction has been approved on behalf of NHS Cambridgeshire by:

Name	Designation/Title	Signature	Date
Sati Ubhi	Deputy Chief Pharmacist	Signed on	30.11.2011
Dr Christine Macleod	Medical Director	Signed on	29.11.2011

Authorisation of Employer (if not employed by NHS Cambridgeshire):

Name	Designation/Title	Signature	Date

Patient Group Direction for Administration of Combined Diphtheria, Tetanus, acellular Pertussis, inactivated Polio and Haemophilus influenzae type b vaccine DTaP/IPV/Hib Primary Immunisation to Children aged 2 months to 10 years

Action required before proceeding with administration and/or supply of a vaccine /medication under this Patient Group Direction

Each registered practitioner authorised to administer medication under this PGD must have read, understood and signed this version of the PGD and completed the agreement to practice form before attempting to work to it.

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence.

It is the responsibility of each individual practitioner to confirm before each administration that the information within this PGD is 'up-to-date'.

In the event that the information links no longer work, or the PGD has expired, please notify NHS Cambridgeshire's Medicines Management Team. In such circumstances a Patient Specific Direction (PSD) is indicated.

In order for administration and/or supply of the vaccine/medication under this PGD to be valid, practitioners should have electronic access to, or a hard copy of, the most recent information relating to the named vaccine:

- **Childhood Immunisation Schedule** (Department of Health, 2010), available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_122401.pdf
- **Relevant chapter(s) of 'The Green Book' – Immunisation against infectious disease** (Department of Health, 2006), available via http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917
- **Summary of Product Characteristics from the electronic Medicines Compendium (eMC)**, available via <http://www.medicines.org.uk/EMC/default.aspx>
- **British National Formulary**, available online at <http://bnf.org/bnf/bnf/current/> (Athens login required)
- **Patient information leaflets from the electronic Medicines Compendium (eMC)**, available via <http://www.medicines.org.uk/EMC/default.aspx>

Vaccination information for members of the public (NHS Choices, 2011), is available at <http://www.nhs.uk/Planners/vaccinations/Pages/Landing.aspx>

Further immunisation information for health care professionals (Department of Health, 2011), is available at <http://www.dh.gov.uk/en/Publichealth/Immunisation/index.htm>

Further information relating to Healthcare professional reporting adverse reactions (MHRA, 2011), is available at <http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspectedadversedrugreactions/Healthcareprofessionalreporting/Adversedrugreactions/index.htm>

The original copy, signed by all those concerned, should be kept in a designated safe place within the practice, and readily accessible to all registered nurses for reference.

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1. Characteristics of Staff	
1.1 Professional qualification	This PGD is agreed for use by Registered Nurses undertaking immunisation/vaccination
1.2 Additional requirements	<ul style="list-style-type: none"> • Resuscitation skills & anaphylaxis training • Competent to undertake immunisations <p>All authorised staff must demonstrate an appropriate level of understanding and knowledge with regards to:</p> <ul style="list-style-type: none"> • Assessment of patient • The medication, therapeutic use, contraindications, side-effects, interactions and storage and handling requirements • Be familiar with relevant NHSC medicines policies • Have access to local and national guidance as outlined on page 2
1.3 Continued training requirements	<ul style="list-style-type: none"> • Annual attendance at the PCT 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)
2. Clinical condition or situation to which the direction applies	
2.1 Indication	<ul style="list-style-type: none"> • Given as part of the scheduled primary vaccination programme • Active immunisation against diphtheria, tetanus, acellular pertussis, Inactivated poliomyelitis and <i>Haemophilus influenzae</i> type b conjugate vaccine (adsorbed)
2.2 Criteria for inclusion	<ul style="list-style-type: none"> • Any child aged from 2 months and up to 10 years of age as: <ul style="list-style-type: none"> – Primary Immunisation (usually the first year of life) – DTaP/IPV/Hib should be used to complete a primary course that has been started with a whole-cell or another acellular pertussis preparation – To complete a primary course of diphtheria, tetanus, pertussis, Hib and Polio immunisation – If the primary course is interrupted it should be resumed but not repeated, allowing an interval of one month between the remaining doses • Please note: <ul style="list-style-type: none"> – Pediacel ® is licensed for use in children from 2 months up to 4 years of age <p>Refer to section 2.3 Exclusions for this PGD for complementary information and 3 Medicine to be administered under this PGD (off-label use) and 3.9 Cautions. For further details refer to the BNF, Green Book and SPC. Also visit the Health Protection Agency (HPA) website for further details about 'Vaccination of Individuals with Uncertain or Incomplete Immunisation Status'</p>

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	<p>For individuals coming from other countries, please visit the World Health Organisation (WHO) website 'World Health Organisation country-by-country vaccination schedules and coverage information'</p> <p>For all listed vaccines please refer to the appropriate PGD as instructions for specific cases overlap and complement each other</p>
<p>2.3 Criteria for exclusion</p>	<ul style="list-style-type: none"> • No valid consent • Infants under 2 months of age • Acute, severe febrile illness • A true anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis, inactivated polio and Hib • A true anaphylactic reaction to neomycin, streptomycin or polymixin B, or any other component of the vaccine (see SPC) • Individuals over 10 years of age • Evidence of an evolving neurological abnormality <p>NB Patients may be excluded by cautions or interactions</p> <p><i>Where there is doubt, appropriate advice should be sought from a consultant paediatrician, immunisation coordinator or consultant in communicable disease control, rather than withhold immunisation. Specialist advice must be sought on the vaccines and circumstances in which they could be given</i></p> <p>The risk to the individual of not being immunised must be taken into account</p> <p>For further details please refer to the Green Book and the SPC and/or contact the manufacturer</p>
<p>2.4 Action if excluded</p>	<ul style="list-style-type: none"> • Offer advice on when individuals may have the vaccine • Discuss with the patient/client/guardian and document the reasons for exclusion from treatment under the PGD • Reschedule or refer/transfer to the appropriate prescriber/service as soon as clinically appropriate • Specialist advice must be sought on the vaccine/medication and circumstances under which they could be given • The risk to the individual of not being immunised must be taken into account
<p>2.5 Action if patient declines treatment</p>	<ul style="list-style-type: none"> • Advise about protective effects of the vaccine/medication and the risks of infection and disease complications. • Document refusal and advice given in the patient record • Inform or refer to GP as appropriate • Offer disease avoidance advice if travelling
<p>2.6 Reasons for referral or seeking medical advice</p>	<ul style="list-style-type: none"> • Exclusions or patient/guardian preference • Emergency treatment of anaphylactic reactions: Guidelines for Healthcare Providers (Resuscitation Council (UK), 2008) available online at

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	<p>http://www.resus.org.uk/pages/reaction.pdf with the following algorithm</p> <p>http://www.resus.org.uk/pages/anaalgo.pdf</p> <ul style="list-style-type: none"> • In the event of an adverse reaction refer for medical advice • If there are any concerns or cautions/interactions relating to the medicine to be given, practitioners should seek medical advice or refer/transfer to the appropriate prescriber/service if necessary
3. Description of Treatment	
3.1 Name, strength & formulation of drug	Pediacel ® vaccine (<i>Sanofi Pasteur MSD</i>) – <i>Diphtheria, tetanus, five component acellular pertussis, inactivated poliomyelitis and Haemophilus influenzae type b conjugate vaccine (adsorbed) (0.5ml)</i>
3.2 Legal status	POM (Prescription Only Medicine)
3.3 ▼ Black triangle?	No
3.4 PGD covering use outside terms of Summary of Product Characteristics?	<ul style="list-style-type: none"> • Administration of Pediacel ® to children over the age of 4 years is outside the terms of the SPC. • However, Primary Immunisation with this vaccine up to the age of 10 years is in accordance with Department of Health recommendations as laid down in the Green Book 'Immunisation against infectious disease' • Please explain to the patient/parent/guardian that advice differs from the patient information leaflet and the reason for this
3.5 Route/method of administration	<ul style="list-style-type: none"> • Pediacel ® vaccine can be given at the same time as other vaccines but at a different injection site – preferably in different limbs, or if given in the same limb they should be given at least 2.5cms apart • Needles and syringes should be not used for more than one vaccine • Pediacel ® vaccine should be administered via the intramuscular route except where there is a bleeding disorder when the deep subcutaneous route should be used • NB Shake the vaccine well immediately before use
3.6 Dose	0.5ml – single dose
3.7 Frequency of administration	<ul style="list-style-type: none"> • Primary course of vaccination • Three doses to be administered at 2,3 and 4 months of age, or at monthly intervals • If the primary course is interrupted it should be resumed but not repeated, allowing an interval of one month between the remaining doses
3.8 Cautions	<ul style="list-style-type: none"> • IMPORTANT : The first immunisation of a child born very prematurely should be administered in hospital. If the child reacts to the first immunisation, they should return to hospital for their second immunisation • If any of the following events have occurred after a previous dose of pertussis-containing vaccine the decision to give this vaccine should be carefully

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	<p>considered:</p> <ul style="list-style-type: none"> - Temperature of 40°C within 48 hours, not due to another identifiable cause - Hypotonic-hypo-responsive episode (HHE) (please see section 3.10 Potential adverse reactions) - Persistent, inconsolable crying lasting more than 3 hours occurring within 48 hours of vaccination - Convulsions with or without fever occurring within 3 days of vaccination - Severe local reaction, irrespective of extent • However, the Green Book advice that immunisation with DTaP/IPV/Hib containing vaccine should continue following a history of the above mentioned cases. It also mentions that ‘children who have had severe reactions, as above, have continued and completed immunisation with pertussis-containing vaccines without recurrence of these reactions’ (Vermeer-de Bondt et al., 1998; Gold et al., 2000). It also mentions that ‘In Canada, a severe general or local reaction to DTaP/IPV/Hib is not a contraindication to further doses of the vaccine’ (Canadian Medical Association, 1998) • Please refer to the Green Book for further details and if appropriate and/or not sure please seek expert immunisation advice
<p>3.9 Interactions with other medicines See also any interactions listed as exclusions</p>	<ul style="list-style-type: none"> • See SPC, BNF and/or contact the manufacturer • The immunogenicity of the vaccine may be reduced by immunosuppressive treatment or immunodeficiency • The vaccine should not be mixed with other vaccines in the same syringe
<p>3.10 Identification & Management of Adverse Drug Reactions</p>	<ul style="list-style-type: none"> • Very common – Local reactions (pain, erythema and oedema) • Common – Anorexia, diarrhoea, vomiting, irritability, malaise • Rare – Febrile convulsions • Very rare – Inconsolable crying, high fever (>40.5°C) • Anaphylaxis • Hypotonic-hypo-responsive episode (HHE) may occur, usually 1-12 hours after vaccination and may last from a few minutes
<p>3.11 Reporting procedure of Adverse Drug Reactions</p>	<ul style="list-style-type: none"> • Report any suspected ADR to a medical practitioner as soon as possible • Patients with unusual or persistent side effects should be reviewed by the GP • Any serious adverse reaction to the vaccine/medication should be documented in a child’s health records and on their medical records. GP should also be informed. • For established medicines, report all serious suspected reactions in adults, and all serious AND minor reactions in children (under 18 years) via the Yellow Card reporting scheme • For medicines showing the black triangle ▼ symbol ALL suspected ADRs should be reported via the Yellow Card reporting scheme

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3.12 Patient advice	<ul style="list-style-type: none"> • Inform possible side effects and their management • Give advice on temperature control • Always provide the manufacturers Patient Information Leaflet and any specific local/national leaflets to patient/parent/guardian as appropriate. Where a vaccination is given outside of the terms of the Summary of Product Characteristics, discuss and document in the patient's records • Explain treatment and any further instructions to aid compliance/concordance • Advise the patient/patient/guardian to seek medical advice in case of severe or unexpected adverse events • Refer to the Green Book and SPC for further details
3.13 Follow up treatment	<ul style="list-style-type: none"> • Pre-school booster according to scheduled vaccination programme
3.14 Storage and Handling	<ul style="list-style-type: none"> • Pediacel ® - the vaccine should be used as supplied; no dilution or reconstitution is necessary • Vaccines should be maintained at a temperature of +2° to +8°C. If the vaccine has been frozen, the vaccine should be discarded • Store in the original package in order to protect from light • Disposal should be by incineration at a suitably authorised facility • Before use, nurses should satisfy themselves that the vaccine has been properly stored and that the cold chain has not been broken

Please note:

Listed above are the interactions with commonly used medicines and the main side effects. If the patient/client is taking a medicine not listed above or reports side effects refer to the current BNF, Patient information Leaflet or electronic Medicines Compendium <http://www.medicines.org.uk/emc/default.aspx> or seek advice from pharmacist or medicines information department

4. Facilities and supplies that must be available	
4.1 Medicine to be stocked	Pediacel ® vaccine (Sanofi Pasteur MSD) – Diphtheria, tetanus, five component acellular pertussis, inactivated poliomyelitis and Haemophilus influenzae type b conjugate vaccine (adsorbed)
4.2 Storage	<ul style="list-style-type: none"> • Lockable, monitored medicines refrigerator maintained between +2°C and +8°C
4.3 Reporting incidents	<ul style="list-style-type: none"> • Incidents and near misses must be reported using the NHS Cambridgeshire Incident Reporting form (DATIX), which should be forwarded to the Risk Manager as soon as possible AND/OR via employer's critical incident reporting system
4.4 Other requirements	<ul style="list-style-type: none"> • Working telephone and/or access to emergency assistance • Anaphylaxis policy • Immediate access to Epinephrine (Adrenaline) 1in 1000 injection

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	<ul style="list-style-type: none"> • Current BNF • Access to National Guidance – eg Green Book • Access to SPC • Supplies of Patient Information Leaflets
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5. Records to be kept for audit purposes

5.1 Patient details	<ul style="list-style-type: none"> • Patient identifiers • Allergies • Any reason for exclusion and action taken • Document patient consent or refusal • Advice sought from medical/specialist service • Details of any adverse reactions experienced by the patient and action taken • Verbal and written advice given to patient • Follow up and referral details
5.2 Records of administration	<ul style="list-style-type: none"> • In all cases manual records and computer records should include : <ul style="list-style-type: none"> ○ Patient's name and date of birth ○ Dose, site and route of injection/medication ○ Brand, batch number and expiry date of vaccine ○ Date given and by whom ○ Consent given and if a child by whom <p>Where vaccination is given to a child, this should also be recorded in the Child Health Record (PCHR red book)</p>
5.3 Audit	<ul style="list-style-type: none"> • Annual audit must be carried out by the clinical lead or nominated deputy within each practice • A computer or manual record of all individuals receiving immunisation under this Patient Group Direction should also be kept for audit purposes within each practice • Regulations require that there is a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient-by-patient basis • Audit may include evidence of authorised practitioner signatures, appropriate supply, standards of documentation, follow-up arrangements, advice and information given to patients, reporting of adverse effects and incidents

6. References

Department of Health (2006) **The Green Book – Immunisation against infectious disease**, available online at

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917 (accessed 16.11.2011).

Department of Health (2010) **Childhood Immunisation Schedule**, available online at

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_12240_1.pdf (accessed 26.11.2011).

Department of Health (2011) **Immunisation information for health care professionals**, available online at <http://www.dh.gov.uk/en/PublicHealth/Immunisation/index.htm> (accessed 26.11.2011).

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Electronic Medicines Compendium (2011) **Summary of Product Characteristics for PEDIACEL** © (Sanofi Pasteur MSD Limited), last updated on the eMC website 17/05/2010, available online at <http://www.medicines.org.uk/EMC/medicine/15257/SPC/PEDIACEL/> (accessed 16.11.2011).

Health Protection Agency (HPA) (2011) **Vaccination Immunisation**, available online at http://www.hpa.org.uk/infections/topics_az/vaccination/vac_guidelines.htm (accessed 26.11.2011).

Medicines and Healthcare products Regulatory Agency (MHRA) (2011) **Healthcare professional reporting: Adverse drug reactions**, available online at <http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspectedadversedrugreactions/Healthcareprofessionalreporting/Adversedrugreactions/index.htm> (accessed 26.11.2011).

NHS Choices (2011) **Vaccinations: Your NHS guide to vaccinations for you and your family**, available online at <http://www.nhs.uk/Planners/vaccinations/Pages/Landing.aspx> (accessed 26.11.2011).

Resuscitation Council (UK) (2008) **Emergency treatment of anaphylactic reactions: Guidelines for healthcare providers**, available online at <http://www.resus.org.uk/pages/reaction.pdf> (accessed 26.11.2011).

AGREEMENT BY HEALTH PROFESSIONAL TO ACT UNDER THE PATIENT GROUP DIRECTION

I have read and fully understand the following:

Patient Group Direction for Administration of Combined Diphtheria, Tetanus, acellular Pertussis, inactivated Polio and Haemophilus influenzae type b vaccine DTaP/IPV/Hib Primary Immunisation to Children aged 2 months to 10 years

Issue date: 1st December 2011

Expiry date: 30th November 2013

BNF and SPC monographs (and for Immunisation & Vaccination, the appropriate chapters of the Green Book) for all drugs included in this PGD.

NHS Cambridgeshire Patient Group Direction Policy

- I agree to act within the terms of the Patient Group Direction and administer and/or supply medicines in accordance with the documents listed above.
- I understand that my employer e.g. GP practice or NHS Cambridgeshire, is vicariously liable for acts and omissions by me during my employment with them.
- I understand that failure to comply with the terms and conditions of the PGD, including the expiry date and limitations on practitioners, patients, drugs and indications may render me liable to disciplinary action by my employer e.g. GP practice or NHSC under their performance and conduct arrangements.

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTICE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE

Name: *(block capitals)* (Health Professional)

Signature: (Health Professional)

Position:

GP Lead:

Site/Practice:

Date signed:

The original must be filed in the health professional's personal file and a copy held by their manager or employer for the purposes of ensuring practice occurs only in accordance with the PGD and is only undertaken by approved practitioners.

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