Patient Group Direction (PGD) for the Administration of

COMBINED DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS and INACTIVATED POLIO AND HIB VACCINE (DTaP/IPV/Hib – PEDIACEL® and Infanrix® IPV + Hib)

by Registered Professionals to Individuals Accessing NHS Services in Cumbria and North East Sub Region (NHS England North)

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

Direction Number: - **NECSAT 2016/009**

Valid from: 1st September 2016

Review date: 1st May 2018

Expiry date: 31st August 2018

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
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This PGD has been approved for use in Cumbria and North East Sub Region (NHS England) by:			
Title	Name	Signature	Date
Assistant Medical Director (NHS England Cumbria and North East)	**Dr Jonathan Slade** *(Governance Authorisation)*		24/08/16

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

For active immunisation against diphtheria, tetanus, pertussis, poliomyelitis and invasive infections caused by *Haemophilus influenzae* type b, in children aged from 2 months to 10 years of age.

Objectives of care

To prevent infectious disease and promote health. To reduce morbidity & mortality and to eradicate disease.

Inclusion criteria (as per Public Health England (PHE) Green Book Guidance (Sept. 2013))

Only use those criteria that are specific to your authorised role & competence.
Ensure appropriate consent has been obtained before commencing any vaccination.

Any child aged from 2 months up to 10 years of age: -

- As a primary (1°) course in previously un-immunised children or where there is an unreliable or no history of previous immunisation against diphtheria, tetanus, pertussis, poliomyelitis and Hib.
- To complete a primary immunisation course of vaccination against diphtheria, tetanus, pertussis, poliomyelitis & Hib

(See Green Book online updated chapters 15, 16, 24, 26 & 30 for full details and additional information)

Exclusion criteria (Refer to current SPC and Green Book Guidance (Online version) for additional details)

- Children under 2 months of age and over 10* years old
- No valid consent;

(* Pediacel off-label for patients from 4 years of age & Infanrix-IPV + Hib off-label from 3 years of age, but Green Book recommends can be used up to 10 years of age).

- Very premature infants (born ≤ 28 weeks of gestation), who have apnoea, bradycardia or desaturations after the first immunisation, the second dose should be given in hospital (refer to Green Book Chap 11 page 84 online).
- Patient is acutely unwell (postpone vaccination until recovered. Minor infections without fever or systemic upset are not reasons to postpone immunisation).
- A confirmed anaphylactic or severe hypersensitivity reaction to any component, ingredient, or excipient of the vaccine (including neomycin, streptomycin, polymyxin B, polysorbate 80, glutaraldehyde, formaldehyde and bovine serum albumin). – (**refer to precautions section)**
- Severe hypersensitivity to one or more of the antigenic components (i.e. diphtheria, tetanus, pertussis, inactivated polio and Hib) - **(please also refer to precautions section)**
- Have experienced encephalopathy/encephalitis of unknown aetiology, occurring within 7 days of administration of a previous dose of any pertussis containing vaccine. Defer further immunisation until underlying cause has been identified or child is known to have recovered completely within 7 days and paediatrician has advised that further immunisation can go ahead, (Refer to Green Book online)
- Have a pre-existing evolving/progressive neurological condition (including infantile spasms, unstable epilepsy and uncontrolled encephalopathy). Defer immunisation until condition has stabilised or cause identified. Personal history of fitting (seek specialist medical advice). (See Green Book Chapter 24 page 16 online).
- Have had a fever-associated seizure of unidentified cause within 72hrs of an immunisation & child did not recover within 24hrs.

Precautions

- Individuals with immunosuppression and HIV infection should still be vaccinated according to the schedule. These individuals may not make a full antibody response and re-immunisation should be considered. Specialist advice may be required
- Hypersensitivity reactions to previous dose of vaccine or component of vaccine:
  - **NB**. "Local adverse reactions that generally start within a few hours of the injection and are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens"

Action if excluded

- Discuss with or refer to clinician/doctor.
- Ensure all actions/decisions are documented.
- The risk to the individual of not being immunised must be taken into account.
- If postponement due to acute illness, arrange a future date for immunisation.
- Seek specialist advice if excluded due to existing evolving or progressive neurological condition or a personal history of fitting.

Circumstances in which further advice should be sought from doctor and/or specialist

- **In children with a progressive, evolving or unstable neurological condition.**
- **In children on immunosuppressive treatment or with immunodeficiency.**

Please refer to current SPC "special warnings & special precautions for use" section for full details & relevant online chapters of the Green Book.

Action if patient declines treatment

- Ensure patient/guardian/carer fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications.
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate.

Special Considerations / Additional Information

- **DTaP/IPV/Hib vaccine can be given at the same time as other vaccines, but at a different injection site – either in different limbs, or at least 2.5cm from the concomitant immunisation.**
- Those who commenced vaccination with oral polio vaccine can complete the course with IPV-containing vaccines.
- Immunisation with pertussis containing vaccine should continue following a history of fever (irrespective of severity); hypotonic-hyporesponsive episodes (HHE); Persistent crying or screaming for >3hrs; severe local reaction (irrespective of extent).
- Children who have had a local or general reaction after a whole-cell pertussis vaccine should complete their immunisation with acellular pertussis preparations.
- Very premature infants (born ≤28weeks gestation) who are in hospital should have respiratory monitoring for 48 to 72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity.
- Very premature infants (born ≤28wks gestation) who have been discharged from hospital may be safely immunised in primary care
- If the premature infant has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should be given in hospital, with respiratory monitoring for 48-72hours.
- Store in a refrigerator (+2°Cto +8°C). **Do not freeze**. Keep the container in the original packaging in order to protect from light
- **Stability Data:** Infanrix-IPV+Hib only: After reconstitution, the vaccine should be injected immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should normally not be longer than 8 hours at +2°C to +8°C (in a refrigerator).

(Please see Green Book – Online version, Chapters 15, 16, 24, 26 & 30 and the manufacturer's SPC)

2. Description of Treatment.

Name, strength & formulation of drug

PEDIACEL® (DTaP/IPV/Hib) - Sanofi Pasteur MSD Limited

- Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and *Haemophilus influenzae* type b conjugate vaccine (adsorbed) in the form of a suspension in pre-filled syringe (type I glass) with a plunger stopper (halobutyl elastomer), without attached needle, with a tip-cap (halobutyl elastomer)
- PEDIACEL is a uniform, cloudy, white to off-white suspension, which may sediment during storage
- The vaccine should be used as supplied; no dilution or reconstitution is necessary. Shake the pre-filled syringe well to uniformly distribute the suspension before administering the vaccine

INFANRIX® IPV + Hib - GlaxoSmithKline Ltd

- Diphtheria, tetanus, pertussis (acellular component), poliomyelitis (inactivated) and *Haemophilus influenzae* type b conjugate vaccine (adsorbed) in the form of a powder in vial (type I glass) with stopper (butyl rubber) with a 0.5 ml suspension in pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) with or without needles
- **The two components must be mixed according to the manufacturers' instructions before administration**
- The diphtheria, tetanus, acellular pertussis & inactivated poliomyelitis (DTPa-IPV) component (in the pre-filled syringe) is a turbid white suspension. The lyophilised *Haemophilus influenzae* type b (Hib) component (in the vial) is a white powder.

Legal Status:

POM –Prescription Only Medicine

(The use of the vaccine in this PGD is off-label but follows current Public Health England guidance)

Dosage/Dose range:

0.5ml (1 single dose)

Route/Method:

Intramuscular injection (IM) is the preferred route: -

- Anterolateral aspect of thigh in infants; deltoid region in older children.
- **Not** to be given intravenously.
- Vaccination by deep sub-cut route ***only*** for individuals with a bleeding disorder, e.g. thrombocytopenia.)

Frequency of Administration: (Refer to PHE Green Book Guidance for additional details)

PLEASE NOTE: Infanrix IPV+Hib and Pediacel are interchangeable, however, whenever possible, the same DTaP-IPV/Hib containing vaccine product should be used for all three doses of the primary vaccine course. If this is not possible, whichever primary vaccine is available (Pediacel or Infanrix IPV+Hib) should be used. Vaccination should not be delayed because the vaccine used for previous doses is unavailable or not known, (Vaccine update. Issue 216, June 2014).

AGE	PRIMARY IMMUNISATION COURSE: -
2 months of age to under 10 years old	**Three (3) doses** Administered at two, three & four months of age (1 month interval between doses) • **Interrupted primary courses: -** Should be resumed but not repeated. Allow interval of 1 month between remaining doses. • **Children with unknown or incomplete immunisation status: -** A maximum of three doses administered at 1 month intervals depending on their previous immunisation history. Please refer to the PHE guidance on the "vaccination of individuals with uncertain or incomplete immunisation status"

Please refer to the Immunisation Against Infectious Diseases (Green Book), online Chapters 15, 16, 24, 26 & 30 for full details.

Maximum dose / Maximum number of vaccinations:

Maximum dose: **0.5ml** Maximum no. of vaccinations: **Three (3)**

Follow up treatment:

As per current DH and PHE Immunisation Schedule: https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule

3. Further Aspects of Treatment:

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See Manufacturers SPC for full details / current Green Book online

Potential Adverse Effects/ Reactions: -

Very Common & Common reactions	• Injection site tenderness/pain, erythema & oedema. Irritability, increased crying, fever (>38°C). (Local reactions within 48hrs after vaccination and persisting for 1-2 days). • Decreased appetite, diarrhoea and vomiting. Decreased activity. Somnolence
Uncommon, rare and very rare	• Febrile convulsions, with or without fever (If occur then seek doctor/medical advice); • High fever (> 39.5°C); High pitched crying; • Extensive limb swelling (from injection site beyond one or both joints). Anaphylactic reaction. • Upper respiratory tract infection; Urticaria and rash

See Manufacturers SPC for full details of all potential adverse reactions.

Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- **Advice on management including anaphylaxis**: - Chapter 8 of the Green Book provides detailed advice on managing ADRs following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor if appropriate. **Please be aware of Resuscitation Council Guideline changes (2015)**

Please refer to current SPC "special warnings & special precautions for use" section for full details & relevant online chapters of the Green Book.

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All suspected Adverse drug reactions to vaccines occurring in children, or in individuals of any age after vaccines labelled with a black triangle (▼), should be reported to the MHRA using the yellow card scheme.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and Green Book online - Chapter 9

See manufacturers Summary of Product Characteristics for details of all potential adverse reactions.

Advice to Patient / Carer (verbal or written)

- Explain protection level expected from vaccine.
- Provide a patient information leaflet and discuss as required.
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above and manufacturers SPC).
- Explain procedure for dealing with anaphylaxis /severe allergic reactions. Explain the "Out of Hours" procedure.
- Give date of next vaccine if applicable.
- Complete patient-held vaccination record
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.

Arrangements for Referral to Medical Advice

- Doctor appointment as and when appropriate

Records

In all cases manual records including the Personal Held Child Record, computerised records and data collection for Child Health Information Services (CHIS) should include: -

- Patient's name and date of birth;
- Reason vaccination required;
- Dose, site and route of injection;
- Date of administration;
- Brand name, batch number & expiry date of vaccine;
- Whom administered by & signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed; Support literature given (if applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.

Additional Facilities

- Access to a current BNF and online Green Book information
- Store in a refrigerator (+2°C to +8°C). Discard if frozen. Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline as applicable)

References

- ***NHS Executive HSC 2000/026*** (9th August 2000): Patient Group Directions [England only].
- **NICE Good Practice Guidance** : Patient Group Directions Aug 2013
- ***NHS England,*** Immunisation Against Infectious Disease) – (The Green Book online): Chapter 15 (Diphtheria), Chapter 16 (Haemophilus influenza type b), Chapter 24 (Pertussis), Chapter 26 (Poliomyelitis), Chapter 30 (Tetanus). Accessed at https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book on 01/07/2016
- **Public Health England: Vaccination of individuals with uncertain or incomplete immunisation status**. Accessed at: https://www.gov.uk/government/collections/immunisation
- **Public Health England: Routine immunisation Schedule from Summer 2016** accessed at: https://www.gov.uk/government/collections/immunisation
- ***British National Formulary (BNF)***, current edition. Available at http://www.bnf.org/bnf/index.htm
- ***Nursing and Midwifery Council (NMC), 2007***: Standards for Medicines Management.
- ***Nursing and Midwifery Council (NMC), 2007***: Record Keeping Advice Sheet.
- ***Nursing and Midwifery Council (NMC), 2008***: Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- ***Resuscitation Council (UK), October 2015***: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- Sanofi Pasteur MSD Limited, Pediacel® - ***Summary of Product Characteristics*** (SPC), 25/02/2014 (accessed from Electronic Medicines Compendium (EMC) on 04/07/2016).
- GlaxoSmithKline UK, Infanrix-IPV+Hib® - ***Summary of Product Characteristics*** (SPC), 19/02/2015 (accessed from EMC on 04/07/2016).
- NHS England, February 2016: **NHS public health functions agreement 2016-17 - Service specification No.4** - Immunisation against diphtheria, tetanus, poliomyelitis, pertussis and Hib programme

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists
State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.		

Qualifications required (professional registration applies to specific professions**)**

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council

Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the HPA National minimum standards in immunisation training 2005 either through training or professional competence ensuring that annual training is offered to all staff
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and *Immunisation against infectious disease* (Green Book).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

Continued training requirements (applies to all staff)

- Annual attendance at an update on resuscitation skills and the management of anaphylaxis within the community/primary care **(mandatory).**
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation **(recommended).**
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- Each healthcare professional should have access to their own signed copy of the full PGD.
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:-_____

I have read and understood the Patient Group Direction.

Combined DTaP/IPV/Hib VACCINE (Pediacel ® and Infanrix® IPV + Hib)

I agree to administer Combined DTaP/IPV/Hib vaccine only in accordance with this Patient Group Direction (NECSAT 2016/009)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

I agree that the above named healthcare professional is authorised to administer medicines in accordance with this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from: 1st Sept 2016	Review Date: - May 2018	**Expiry Date: - 31st Aug 2018**

Management & Monitoring of Patient Group Direction NECSAT 2016/009

DTaP/IPV/Hib (PEDIACEL® and Infanrix® IPV + Hib) vaccine

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

DTaP/IPV/Hib (PEDIACEL® and Infanrix® IPV + Hib) vaccine under the Patient Group Direction (NECSAT 2016/009)

PGD Valid from date: 1st September 2016 **PGD Expiry Date:** 31st August 2018

Healthcare Professional			**Authorised by:**		
Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

PGD Valid from: 1st Sept 2016	Review Date: - May 2018	**Expiry Date: - 31st August 2018**