NHS England Midlands and East (Central Midlands): for use in South Midlands and Hertfordshire

PATIENT GROUP DIRECTION (PGD)

Patient group direction for:

**Primary Diphtheria/Tetanus/acellular Pertussis/Inactivated Poliomyelitis Virus/*Haemophilus influenzae* type b vaccine (DTaP/IPV/Hib: Pediacel® and Infanrix-IPV+Hib®)** for children aged 2 months to less than 10 years

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| **Approved by:** | NHS England Midlands and East (Central Midlands: South Midlands and Hertfordshire) |
| **On:** | 16th September 2015 |
| **Expiry date:** | 31 March 2018 |
| **Directorate responsible for review:** | Screening and Immunisation Team |
| **Policy number:** | SMH SIPGD 008 |

**The master version of this document is held at:**
**SMH SIPGD 008 Pediacel and Infanrix-IPV+Hib signed.doc**

**Change history:**

| Version number | Change details | Date |
|---|---|---|
| 1.0 | First version | 25 March 2015 |
| 1.1 | Leicestershire/Lincolnshire PGD amended for use in South Midlands and Hertfordshire, content otherwise unchanged | 16th September 2015 |

## Contents



## Introduction

Registered nurses must be aware of their legal position when administering a vaccine that has not been individually prescribed by a doctor or other independent prescriber. Since August 2000, Patient Group Directions (PGDs) have become the legal mechanism by which a prescription only medicine (POM) can be supplied or administered to a patient for whom no individual prescription exists. All vaccines are in the legal category of POMs. PGDs are written agreements for the supply and administration of medicines to groups of patients who may not be individually identified before presentation for treatment. They can be used for homogenous patient groups where presenting characteristics and requirements are sufficiently consistent to be catered for by such a non-specific direction, although patients who can be identified before they need a specific medicine may receive that medicine on a patient specific basis.

The following PGD enables identified registered nurses to supply and administer immunisations in accordance with national guidelines (Department of Health (DH), 2000; Nursing and Midwifery Council (NMC), 2007; PHE, 2013). The criteria under which individuals will be eligible for inclusion in this PGD are defined within national guidelines (*Immunisation Against Infectious Disease: The Green Book* and subsequent online updates (PHE, 2013).

Immunisation is offered as a health protection activity and as part of both local and national public health programmes against infectious diseases.

In addition to the specific PGD, this document will also provide general guidance for the administration of vaccines.

The NMC document *The code: Standards of conduct, performance and ethics for nurses and midwives* (2008) states that nurses must:

- respect the patient or client as an individual
- obtain consent before they give any treatment or care
- co-operate with others in the team
- protect confidential information

- maintain their professional knowledge and competence
- be trustworthy
- act to identify and minimise the risk to patients and clients

**Characteristics of staff**

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| Qualifications Required | Nurse registered with the Nursing and Midwifery Council (NMC) |
| Additional Requirements | Immediate access to ampoules of Adrenaline (Epinephrine) 1:1000 (1mg/ml) and the necessary means to administer it (syringes and needles). Note that up to 3 ampoules may be required.<br><br>Epipens® and Anapens® are not suitable for the treatment of anaphylaxis other than by patients or their carers.<br><br>Access to '*Immunisation Against Infectious Disease: The Green Book'* (PH, 2013 and subsequent online updates) and comply with its current recommendations; this is available at: https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book<br><br>Training and competence in all aspects of immunisation including contraindications and the recognition and treatment of anaphylaxis. |
| Continuing Training Requirements | Minimum annual update in immunisation and vaccination. Annual basic life support and anaphylaxis update. |

## Due regard

NHS England Midlands and East is committed to equality and means that this PGD has been screened in relation to paying due regard to the general duty of the *Equality Act 2010* to eliminate unlawful discrimination, harassment and victimisation; to advance equality of opportunity and to foster good relations.

This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

It is judged that it is not proportionate (equality relevant) in respect of this PGD as it specifically enables identified registered nurses to supply and administer immunisations in accordance with national guidelines. Due regard has been given in respect of accessibility (larger print, Braille etc.), including the provision of information and advice in other languages and consideration of patient carers and family members for support.

## PGD development

| **Individuals who have been involved in the preparation of this PGD** | |
|---|---|
| Lesley McFarlane, RGN | Screening and Immunisation Co-ordinator, NHS England Midlands and East (Central Midlands: Leicestershire and Lincolnshire) |
| Chloe Leggat, RGN | Screening and Immunisation Co-ordinator, NHS England Midlands and East (Central Midlands: Leicestershire and Lincolnshire) |
| Sue Carr | Principal Pharmacist Medicines Information, Trent Medicines Information Service |
| Vanessa Chapman | Acting Regional Director, Trent Medicines Information Service |

## Approval and authorisation

| Clinical Authorisation | |
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| **Lead Doctor** | Dr Tim Davies, Consultant lead for screening and immunisation, NHS England Midlands and East (Central Midlands: Leicestershire and Lincolnshire)<br><br>Signature:  <br><br>Date: 16th September 2015 |
| **Lead Pharmacist** | Bhavisha Pattani,<br>Controlled Drugs Accountable Officer/Senior Clinical Advisor Pharmacy, NHS England, Midlands & East (Central Midlands)<br><br>Signature:  <br><br>Date: 16th September 2015 |
| **Organisational Authorisation** | |
| **On behalf of** NHS England Midlands and East (Central Midlands) | Dr Aly Rashid, Medical Director<br><br>Signature:  <br><br>Date: 16th September 2015 |
| | |

The PGD **MUST** be easily accessible in the clinical setting.

## Nurse's agreement

The PGD on the following pages is agreed for use by registered nurses working in primary care and the community and undertaking immunisation/vaccination.

Each nurse should have their own copy of the current version of this document available in the clinical room when administering this product. This may include the document being open on a computer screen.

Each nurse should sign and retain a copy of the Individual authorisation form at the back of this document.

## General Guidance

## Consent

All patients for whom vaccination is proposed should give their consent to vaccination. Appropriate written information should be provided to support the process of informed consent where available.

Children:
Consent of the parent or the person with parental responsibility must be obtained prior to administration. In some situations it may be appropriate to obtain consent from a child deemed to be "*Gillick* competent" (Care Quality Commission, 2014). In this event the immunising nurse must ensure that practice is within national and local guidelines and document the decision accordingly (DH, 2009).

## Documentation

A written and/or electronic entry must be made in the patient's medical records. This record must be clear, legible and contemporaneous. Every PGD provides detailed information about what must be included.

In addition, for children:

- the parent-held child's health record ("Red Book") should, ideally, be completed with the vaccination dates;
- the local Immunisation / Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation / pathway.

## Supply and Storage

All vaccines for the routine childhood programmes should be ordered via the ImmForm website. Vaccines for the routine adult programmes should be ordered directly from the manufacturer.

**All vaccines must be stored in the correct conditions in accordance with individual manufacturer's recommendations and the relevant cold chain.**

Please note that vaccines will have different thresholds for use once they have been removed from the cold chain. The relevant information does not usually form part of the manufacturer's Summary of Product Characteristics (SPC), and, if required, should be obtained direct from the manufacturer, or from the local medicines information team – see p10 for details.

## Monitoring

The local Child Health Records Departments, on behalf of NHS England Midlands and East (Central Midlands), monitor the uptake of childhood vaccines within the national programme of immunisation for the DH. Individual general practitioner surgeries are responsible for the monitoring of other immunisation programmes undertaken within the Leicestershire and Lincolnshire area.

**Administration of Vaccines**

Administration steps:

1. Appointment time for immunisation should be long enough to:
   - Assess patient's suitability for immunisation
   - Advise on possible side effects
   - Answer patient's/parent's/carer's queries
2. Obtain informed consent
3. Administer the vaccine
4. Complete all documentation

A doctor is **not** needed on site when administering vaccines; however, a risk assessment should be carried out regarding available help/distance for ambulances to cover etc. in an emergency situation.

Administration process:

Most vaccinations are given as injections. All such vaccines should be given by deep intramuscular injection as per manufacturer's instructions. Individuals with bleeding disorders should have such vaccinations administered by the subcutaneous route unless this is not offered as an option in the *Green Book*, in which case an alternative product should be used or further guidance sought. For all vaccines given by injection:

> **Infants under 1 year should receive vaccines in the anterolateral aspect of the thigh since the deltoid muscle is not sufficiently developed.**
>
> **Over 1 year there is an element of choice between the anterolateral aspect of the thigh or the deltoid muscle.**
>
> **For older children and adults, the deltoid muscle is the preferred site.**

Choice of needle - the correct length and gauge of the needle are key to ensuring that the vaccine is delivered to the correct location as painlessly as possible and with maximum immunogenicity. See also the section on "Immunisation Procedures" in the *Green Book* (PHE 2013) and *UK Guidance on Best Practice in Vaccine Administration* (Vaccine Administration Taskforce, 2001).

Vaccines given at the same time should be administered at different sites, preferably in different limbs, but if the same limb is used the sites should be a minimum of 2.5cm apart and the site of each vaccine should be clearly recorded. Vaccines should **not** be given in the same arm as a BCG for 3 months after the BCG has been given.

Scheduling:

It is important that premature infants have their immunisations at the appropriate chronological age, in preference to gestational age, according to the schedule. The *Green Book* has specific guidance for very premature infants (born on or before 28 weeks' gestation), which must be followed, but, as the benefit of vaccination is high in this group of infants, vaccination should not be unnecessarily withheld or delayed. See: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147976/Green-Book-Chapter-24-dh_125944.pdf, p286 [Accessed 16 May 2014].

## Adverse Effects Following Immunisation (AEFI)

Although adverse outcomes are rare, medical advice should be sought as appropriate. National guidelines are available for nurses, which advise on the appropriate management of anaphylaxis (Resuscitation Council (UK), 2008; National Institute for Health and Clinical Excellence (NICE), 2011).

At any premises where immunisation takes place, the nurse must have access to three ampoules of Adrenaline (Epinephrine) 1:1000 (1mg/ml) injection plus the appropriate syringes and needles. Epipens® and Anapens® are not appropriate and should not be used.

Recipients of any vaccine should be observed for immediate AEFIs. There is no evidence to support the practice of keeping patients under longer observation in the surgery. Advice on the management of immediate AEFIs can be found in Chapter 8 of the *Green Book*.

AEFIs may be true adverse reactions intrinsic to the vaccine or caused by the way it is administered, or may be related to an underlying condition in the recipient. Other AEFIs may be coincidental and would have occurred regardless of vaccination.

Classification of AEFIs:
WHO classifies AEFIs according to four main categories:

- programme-related
- vaccine-induced
- coincidental
- unknown.

**For further information on AEFIs consult *Immunisation Against Infectious Disease: The Green Book* (PHE, 2013) – chapter 8.**

- *Note*: 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. See chapter 8 of the *Green Book* and the NICE guidance to which it refers. However, individual chapters of the *Green Book* may offer different advice for specific vaccines and, where this is the case, such guidance should be followed.

## Reporting Adverse Effects Following Immunisation

Locally:
Vaccine related incidents should be reported locally in line with the incident reporting policy that is current at the time of the incident.

Nationally:
To the Medicines and Healthcare Products Regulatory Agency (MHRA) using the Yellow Card scheme available in the paperback version of the British National Formulary (BNF) (latest edition also available online at: http://www.medicinescomplete.com/mc/bnf/current/)

or from the MHRA (www.mhra.gov.uk). Reporting can be carried out electronically: http://www.yellowcard.gov.uk/.

All suspected adverse drug reactions (ADRs) occurring in children should be reported. The MHRA encourages reporting of suspected ADRs even if there is uncertainty as to whether the vaccine played a causal role.

## Risk Management

The safety of both the nurses administering the vaccine and of clients is paramount. If an immunisation is administered in error, the incident should be reported in line with the incident reporting policy that is current at the time of the incident.

## Suggested Reading/References

To support the information contained within these PGDs, you are recommended to consult additional sources of information where appropriate (see below).

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| Healthcare professionals are reminded that, in some circumstances, the recommendations regarding vaccines given in the *Green Book* chapters may differ from those in the SPC for a particular vaccine. When this occurs, the recommendations in the *Green Book*, which are based on current expert advice received from the Joint Committee on Vaccination and Immunisation (JCVI), should always be followed. |

Further information on any of the products in this document is available from the local Medicines Information Services: Leicester Royal Infirmary, telephone 0116 258 6491, e-mail medicines.info@uhl-tr.nhs.uk or Lincoln County Hospital, telephone 01522 573802, e-mail medicines.information@ulh.nhs.uk.
Generic queries about immunisation can also be directed to england.immsqa@nhs.net

**References underpinning this document:**


Care Quality Commission (2014) **GP Mythbuster 8: Gillick competency and Fraser guidelines** [online]. Available at: http://www.cqc.org.uk/content/gp-mythbuster-8-gillick-competency-and-fraser-guidelines [Accessed 10 February 2015].

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Public Health England (2013) **Immunisation Against Infectious Disease "The Green Book"** [online]. Available at: https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book [Accessed 18 February, 2015].

Department of Health (2009) **Reference Guide to Consent for Examination or Treatment (2nd edition)** [online]. Available at: https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition[Accessed 20 August, 2013].

National Institute for Health and Clinical Excellence (2011) **Anaphylaxis: assessment to confirm an anaphylactic episode and the decision to refer after emergency treatment for a suspected anaphylactic episode, NICE Clinical Guideline 134** [online]. Available at: http://guidance.nice.org.uk/CG134/Guidance/pdf/English [Accessed 20 August, 2013].

Nursing and Midwifery Council (2007) **Standards for medicines management** [online]. Available at: http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-for-medicines-management.pdf [Accessed 20 August, 2013].

Nursing and Midwifery Council (2008) **The code: Standards of conduct, performance and ethics for nurses and midwives** [online]. Available at: http://www.nmc-uk.org/Publications/Standards/The-code/Introduction/[Accessed 20 August, 2013].

Resuscitation Council (UK) (2008) **Emergency treatment of anaphylactic reactions Guidelines for healthcare providers** [online]. Available at: http://www.resus.org.uk/pages/reaction.pdf[Accessed 20 August, 2013].

Vaccine Administration Taskforce (2001) **UK Guidance on Best Practice in Vaccine Administration.** London, Shire Hall Communications.

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

**Diphtheria/Tetanus/acellular Pertussis/ Inactivated Poliomyelitis Virus/*Haemophilus influenzae* type b vaccine (DTaP/IPV/Hib: Pediacel® and Infanrix-IPV+Hib®) for children aged 2 months to less than 10 years**

| **1.Clinical condition or situation to which the direction applies** | |
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| **Indication** | For active immunisation against diphtheria, tetanus, pertussis, poliomyelitis and Hib in children from 2 months, and up to 10 years of age. Given:<br>• as part of the primary course of the childhood vaccination programme<br>• to complete an interrupted primary course of vaccination against these antigens<br>• to vaccinate children with an unknown or uncertain primary immunisation status |
| **Objective of programme** | The objective of the childhood immunisation programme is to provide three primary doses of a high-dose diphtheria, tetanus, pertussis, poliomyelitis and Hib – containing vaccine at appropriate intervals during the first year of every child's life. It is recommended that these are given at ages 2, 3 and 4 months.<br><br>Where vaccination has been delayed after the first birthday, 3 primary doses of high-dose diphtheria, tetanus, pertussis and poliomyelitis – containing vaccines are required: whilst only one dose of a Hib-containing vaccine is required at this age, a 5-component (DTaP/IPV/Hib) vaccine should still be used if the child requires primary doses of any / all of the other 4 antigens. In particular, low-dose diphtheria – containing vaccines should not be used for primary vaccination in children of less than 10 years of age.<br><br>It is recognised and accepted that, in some instances, following this guidance may result in a child receiving more than 3 doses of some components of these primary immunisations. |
| **Criteria for inclusion** | Children aged from 2 months to less than 10 years who have not received a completed a primary immunisation course.<br>• This includes children for whom it cannot be established, with certainty, whether or not they have received the required number of doses of any / all of these antigens. |

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| **Criteria for exclusion**<br><br>Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it would be outside the remit of the PGD and another form of authorisation will be required | The vaccines should not be given to those who have had:<br><br>• A confirmed anaphylactic reaction to a previous dose of a diphtheria, tetanus, pertussis, polio or Hib - containing vaccine.<br>• A confirmed anaphylactic reaction to any component of the vaccine: nurses should check the appropriate SPC for full particulars.<br><br>Note: Pediacel® may contain trace amounts of streptomycin, neomycin, polymyxin B, glutaraldehyde, formaldehyde and bovine serum albumin; Infanrix-IPV+Hib® may contain trace amounts of polysorbate 80; neomycin and polymixin.<br><br>• Previous encephalopathy of unknown aetiology within seven days of previous immunisation with a pertussis-containing vaccine.<br><br>If a child experiences encephalopathy or encephalitis within seven days of immunisation, it is unlikely that these conditions will have been caused by the vaccine; they should be investigated by a specialist, and the advice in the flow chart in Figure 24.4, *Green Book* p 288 should be followed: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147976/Green-Book-Chapter-24-dh_125944.pdf, following which another form of authorisation must be obtained to enable administration of these vaccines to take place at the appropriate time<br><br>• *Current* neurological deterioration.<br><br>The presence of a neurological condition is not a contraindication to immunisation, but, where there is evidence of a neurological condition in a child, the advice given in the *Green Book*, pp 286-287 including the flow chart in Figure 24.3, should be followed: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147976/Green-Book-Chapter-24-dh_125944.pdf and *if* there is evidence of *current* neurological deterioration, including poorly controlled epilepsy, infantile spasms and progressive encephalopathy, immunisation should be deferred and the child should be referred to a specialist for investigation to see if an underlying cause can be identified, following which another form of authorisation must be obtained to enable administration of these vaccines to take place at the appropriate time.<br><br>Note: vaccination should only be deferred in the circumstances specified in the *Green Book*, and the period of deferral should be minimised so that immunisation can |

commence as soon as possible, since the child will be unprotected until vaccinated.

- *Very* premature infants: infants born at or before 28 weeks' gestation.
  It is important that all premature infants have their immunisations at the appropriate chronological age (not their gestational age) according to the schedule. Most *very* premature infants will still be in hospital when their first primary immunisations fall due, and will receive appropriate monitoring. Once discharged, they may need to return to hospital to receive subsequent doses (and monitoring), and the advice of their paediatrician should be sought.

  There is *no* requirement to re-hospitalise a *very* premature baby to receive *any* doses of vaccine, including the first ones, unless the paediatrician's advice is to do so.
  However, all *very* premature infants are excluded from this PGD, and the administration of any of their infant doses of Pediacel® or Infanrix-IPV+Hib® will require another form of authorisation. Steps should be taken to minimise delays to the administration of all vaccines as the child remains unprotected until fully immunised as per the schedule.

- Fever or acute severe systemic illness.

  If an individual is acutely unwell, immunisation should be postponed until they have fully recovered. This is (only) to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine, not because vaccination would be harmful.

**No exclusion for:**

- Minor illnesses without fever or systemic upset.

  These are not valid reasons to postpone immunisation.

- A history of a either a systemic or a local reaction, regardless of severity, within 72 hours of a preceding vaccine.

  Immunisation should continue following a history of:
  - fever
  - hypotonic-hypo-responsive episodes (HHE)
  - persistent crying or screaming for more than three hours
  - a severe local reaction, irrespective of extent.

- A family history of *febrile seizures* or a personal history of

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| | seizure associated with fever in the past, with no evidence of neurological deterioration.<br><br>Neither of these are contraindications and immunisation should proceed as normal.<br>*Note*: when there is a family or personal history of febrile seizures, there is an increased risk of seizure occurring after any fever, including that caused by immunisation. Seizures associated with fever are rare in the first six months of life and most common in the second year of life. After this age the frequency falls and they are rare after five years of age. *Advice on the prevention and management of fever should be given before immunisation.*<br><br>• A *stable* neurological condition.<br><br>The *Green Book* (see link above) also provides clear guidance about the circumstances in which vaccination should proceed<br>• Prematurity: infants born after 28 weeks' gestation.<br><br>It is important that premature infants have their immunisations at the appropriate chronological age (not their gestational age) according to the schedule. |
| **Action if deferred / excluded** | Advise when they may have the vaccine or refer to a consultant in health protection, Public Health England, for specialist advice. |
| **Action if patient declines treatment** | • Advise about the protective effects of the vaccine, and the risks of infection including potential complications.<br><br>• Document advice given and decision reached.<br><br>• Inform, or refer to, their GP. |
| **Reference to national / local policies or guidelines** | *Green Book* chapters 15 (Diphtheria), 16 (Hib), 24 (Pertussis), 26 (Polio) and 30 (Tetanus): https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book<br><br>Sanofi/Pasteur/MSD SPC for Pediacel®, accessed 07.10.14 via: http://www.medicines.org.uk/emc/medicine/26217/SPC/PEDIACEL+syringe/ last date of revision of text 25th February 2014<br><br>Glaxo Smith Kline SPC for Infanrix-IPV+Hib®, accessed 07.10.14 via: http://www.medicines.org.uk/emc/medicine/28678/ last date of revision of text 8th October 2013 |

| 2. Description of treatment | |
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| **Name, strength and formulation of vaccines** | Pediacel® suspension for injection in a pre-filled syringe<br>*and*<br>Infanrix-IPV+Hib® powder (Hib) and suspension for injection (DTaP-IPV)<br><br>Both are diphtheria, tetanus, pertussis (acellular component) poliomyelitis (inactivated) and *Haemophilus influenza*e type b conjugate vaccines (adsorbed) presented as 0.5ml (half a millilitre) doses; both are adsorbed on aluminium compounds.<br>As with all diphtheria, tetanus, pertussis, polio and Hib vaccines, these products can be used interchangeably, but, whenever possible, it is preferable to use the same product for all 3 doses of the primary course. This is because these products have different pertussis components.<br><br>Refer to the SPC for a full list of vaccine components (see **Criteria for exclusion** and **Reference to national / local policies / guidelines** sections above). |
| **Presentation** | • Pediacel® is supplied as a uniform, cloudy, white to off-white suspension for injection, in a glass pre-filled syringe with a plunger stopper and tip-cap (both made of halobutyl elastomer); needles may or may not be supplied.<br><br>○ The vaccine should be used as supplied; no dilution or reconstitution is necessary. The suspension may sediment during storage: shake the pre-filled syringe well to uniformly distribute the suspension before administering the vaccine.<br><br>○ The needle should be pushed firmly on to the end of the pre-filled syringe and rotated through 90 degrees.<br><br>• Infanrix-IPV+Hib® is supplied as a lyophilised white powder (the Hib component) in a glass vial with butyl rubber stopper, and a turbid white suspension (the DTaP-IPV component) in a glass pre-filled syringe with a butyl rubber stopper; needles may or may not be supplied.<br><br>○ The vaccine is reconstituted by adding the entire contents of the pre-filled syringe to the powder in the vial; first shake the suspension, then, once this has been added to the powder, shake the vial vigorously to ensure that all the powder has dissolved. Once the mixture has been drawn back into the syringe, shake the syringe vigorously before immediate administration. DO NOT INJECT THE SUSPENSION WITHOUT FIRST MIXING IT WITH THE POWDER: FAILURE TO DO THIS WILL MEAN THAT THE CHILD DOES NOT RECEIVE THE Hib COMPONENT OF THE VACCINE.<br><br>○ Replace the needle with an appropriate size needle for injection and administer the vaccine. |

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| | ○ If the vaccine is not administered immediately, shake the solution vigorously again before injection. |
| **Storage** | Vaccines should be stored in the original packaging at +2˚C to +8˚C and protected from light. All vaccines are sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Effectiveness cannot be guaranteed for vaccines unless they have been stored at the correct temperature. Freezing should be avoided; it may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents. |
| **Legal status** | Prescription Only Medicine (POM) |
| **Black Triangle▼** | No |
| **Route / Method** | Both vaccines should be given intramuscularly into an age-appropriate site (see **Administration of Vaccines** in the guidance notes preceding this PGD). However, for individuals with a bleeding disorder, the vaccines should instead be given by deep subcutaneous injection to reduce the risk of bleeding. Firm pressure should be applied to the injection site (without rubbing) for at least two minutes. |
| **Dose** | 0.5ml |
| **Frequency of administration** | Administered at one month intervals (that is, following a 0, 1, 2 month regimen, starting at age 2 months); if this regimen is interrupted it should be resumed but not repeated, allowing an interval of one month between the remaining doses. |
| **Duration of treatment** | Until the completion of 3 three primary doses of all 5 antigens or the child attains 10 years of age, whichever occurs first. Neither Pediacel® nor Infanrix-IPV+Hib® should be used for, or to complete, a primary course of diphtheria, tetanus, or polio vaccination in children of this age and above, nor are pertussis and Hib doses required after the 10th birthday.<br><br>The doses should, ideally, be timed so that the 3rd dose is given at age 4 months.<br><br>Neither Pediacel® nor Infanrix-IPV+Hib® are licensed for children aged over 3 or 4 –see comments from respective SPCs below:<br><br>*"The safety and efficacy of Infanrix-IPV+Hib® in children over 3 years of age have not been established. No data are available."*<br><br>*"Children 4 years of age or older: The safety and efficacy of Pediacel® in children 4 years of age or older has not been established. No data are available."*<br><br>However, the *Green Book* advises vaccination up to 10 years of age. |

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| | Benefit from vaccination is thought to outweigh risks of vaccination in such cases.<br><br>See **Suggested reading / further guidance** regarding discrepancies between the *Green Book* and SPCs |
| **Administer** | One dose on each of a maximum of three occasions. |
| **Total doses** | Total number of doses in primary course: normally 3 but see **Objectives of programme**, above. |
| **Disposal** | Equipment used for immunisation, including used vials, ampoules, or partially discharged vaccines in a syringe or other applicator, should be disposed of at the end of a session by sealing in a proper, puncture-resistant 'sharps' box, according to local authority regulations and DH guidance (2013) *Health Technical Memorandum 07-01: Safe management of healthcare waste* [online]. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/167976/HTM_07-01_Final.pdf. [Accessed 20 August 2013]. |
| **Drug interactions** | As with other vaccines, the immunogenicity of the vaccine could be reduced by immunosuppressive treatment (and conditions, e.g. HIV), *however vaccination is still recommended even if the antibody response might be limited*. Re-immunisation should be considered after treatment is finished and recovery has occurred. Specialist advice may be required.<br><br>Both vaccines can be given at the same time as all other vaccines, whether in the childhood schedule or for travel. The vaccines should be given at a separate site, preferably in a different limb. If given in the same limb, they should be given at least 2.5cm apart. The specific site at which each vaccine was given should be noted in the patient's records. |
| **Identification & management of adverse reactions** | Pain, swelling or redness at the injection site are common and may occur more frequently following subsequent doses.<br><br>A small painless nodule may form at the injection site; this usually disappears and is of no consequence.<br><br>Fever, convulsions, high-pitched screaming and episodes of pallor, cyanosis and limpness (HHE) occur with equal frequency after administration of all DTaP and DT containing vaccines – see **Criteria for exclusion** section for more information (*note*: these are not reasons to defer further doses) |
| **Patient advice and follow up treatment** | See **Advice to patient**(below)<br><br>If the primary course is interrupted, it should be resumed but not repeated, allowing an interval of one month between the remaining doses. |

<table>
<tr><td></td><td>Children of one to ten years who have completed a primary course of diphtheria, tetanus, pertussis and polio but have not received Hib-containing vaccines should receive a single dose of Hib/MenC vaccine</td></tr>
<tr><td>Reporting procedure of adverse reactions</td><td>As with all medicines, healthcare professionals and patients are encouraged to report <u>all</u> suspected adverse reactions occurring in children to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk<br><br>A healthcare professional completing a yellow card should note this in the patient's record. Any serious adverse reaction to the vaccine should be fully documented in the patient's record.<br><br>The patient's GP should also be informed.</td></tr>
<tr><td>Advice to parent / carer including written information</td><td>Supply marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.<br><br>Inform parent / carer of possible local and systemic side effects and their management.<br><br>The parent / carer should be advised to seek medical advice in the event of a severe adverse reaction.</td></tr>
<tr><td>Special considerations and additional information</td><td>There must be immediate access to Adrenaline (Epinephrine) 1:1000 (1mg / ml) injection and access to a telephone.<br><br><u>Doses of adrenaline (epinephrine) by age</u>:<br><br>(* A suitable syringe for small volumes should be used)<br><br>
<table>
<tr><td>Age</td><td>Dose of adrenaline (epinephrine): volumes stated are 1:1000 (1mg/ml) adrenaline</td></tr>
<tr><td>Under 6 months</td><td>150 micrograms IM (0.15ml)*</td></tr>
<tr><td>Over 6 months but under 6 years</td><td>150 micrograms IM (0.15ml)*</td></tr>
<tr><td>6 to 12 years</td><td>300 micrograms IM (0.30ml)</td></tr>
<tr><td>Over 12 years including adults</td><td>500 micrograms IM (0.5ml)<br><br>(300 micrograms IM if patient is small or prepubertal)</td></tr>
</table>
<br>As with all vaccines, consideration should be given to the availability of appropriate medical treatment and supervision in case of an anaphylactic or other serious event following the administration of Pediacel® or Infanrix-IPV+Hib®.</td></tr>
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| **Records** | Record:<br>• That valid informed consent was given<br>• Name of patient, address, date of birth<br>• Name (and signature if the record is a written one) of member of staff who supplied / administered the vaccine<br>• Date of supply/administration<br>• Dose and brand of the vaccine supplied / administered<br>• Route of administration<br>• Batch number and expiry date<br>• Advice given including side effects and their management<br>• Advice given if excluded or declines treatment<br>• Details of any adverse drug reactions and actions taken<br>• Record supplied via Patient Group Direction<br>• Patient information leaflet (PIL) supplied<br><br>All records should be clear, legible and contemporaneous.<br><br>The above information should be recorded in the patient's general practitioner record and, whenever possible, the date of vaccination should also be recorded in the parent-held child health record (Red Book)<br><br>A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.<br>Clinical records must be kept as per national and local policies and guidance and all data must be stored in accordance with Caldicott guidance and the Data Protection Act.<br><br>All suspected adverse reactions should be reported under the Yellow Card scheme (see preceding **General Guidance** section). |
| **3. Characteristics of Staff** | |
| **Qualifications required**<br>Nurses currently registered with the Nursing and Midwifery Council (NMC). | |
| **Additional requirements** | • You must have a working knowledge of, AND access to, the *Green Book* ONLINE and to the CMO/tripartite letters regarding immunisation;<br>• you must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction (PGD) before working to it;<br>• you must have undertaken appropriate training for working under a PGD for the supply and administration of medicines;<br>• you must have undertaken training appropriate to this PGD and be competent to carry out clinical assessment of patients for the immunisation(s) detailed within it;<br>• you must be competent to undertake immunisation and vaccination, and to discuss issues related to them;<br>• you must have undertaken training in the recognition and management of anaphylaxis. |

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| **Continued training requirements** | • It is the responsibility of the individual to keep up-to-date with clinical developments as part of their continued professional development and you should be constantly alert to any subsequent recommendations from the Department of Health and other sources of medicines and vaccine information. |

**Individual authorisation**

**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 and in accordance within *The code: Standards of conduct, performance and ethics for nurses and midwives* (NMC, 2008).**

Note to authorising managers: authorised staff should be provided with an individual copy of this page, showing their authorisation. Authorising managers should retain the original. They should be sure that all staff signed up to use the PGD have the necessary competence, training and knowledge to apply it.

I have read and understood this Patient Group Direction for Diphtheria/Tetanus/acellular Pertussis/Inactivated Poliomyelitis Virus/ *Haemophilus influenzae* type b vaccine (DTaP/IPV/Hib: Pediacel® and Infanrix-IPV+Hib® for children aged 2 months to less than 10 years and agree to supply/administer these medicines only in accordance with this PGD.

I confirm that I have the necessary competence, training and knowledge to apply it.

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| Name of professional: | |
| Signature: | Date: |
| Authorising manager's name: | |
| Signature: | Date: |