Public Health England

NHS England

Document Title:	**Patient Group Direction for administration of Diphtheria, tetanus, pertussis (whooping cough), polio and Haemophilus influenzae type b (Hib) (DTaP/IPV/Hib – Infanrix/IPV/Hib®)**		
AT Doc Ref.:	PGD	**Version No.:**	2/2014
NHS England PGDs Online Access	http://www.england.nhs.uk/mids-east/ss-at/immunisations/		
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File Reference:	\\ims\data\NHS_ENGLAND\AngleseyHouse\Commissioning Directorate\Primary Care & Specialised Commissioning\Public Health\Immunisation\2014-15\10) PGDs\PGD- DRAFTS		
Document Overseeing Group:	PGD Working Group		
Placement in Framework:			
Approval Level:	PGD Oversight and Authorisation Group		
Date of Approval:	September 2014		
Review Date:	September 2016		
Amendment Dates:	**Page(s)**	**Brief Description**	

Patient Group Direction for administration of COMBINED DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS, INACTIVATED POLIO VACCINE AND HIB (DTaP/IPV/Hib – Infanrix® IPV+Hib)

Approved By

NHS England Shropshire and Staffordshire Area Team	Name	Signature
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LPN Pharmacy Chair	**Dr Manir Hussain**	
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Date of patient group direction approved	September 2014
Date this patient group direction becomes due for review	September 2016 or in response to new local/national guidelines.

STAFF CHARACTERISTICS

- Provider of NHS services within NHS England (Shropshire & Staffordshire Area Team)
- Registered nurse with current NMC registration

Specialist competencies or qualifications:

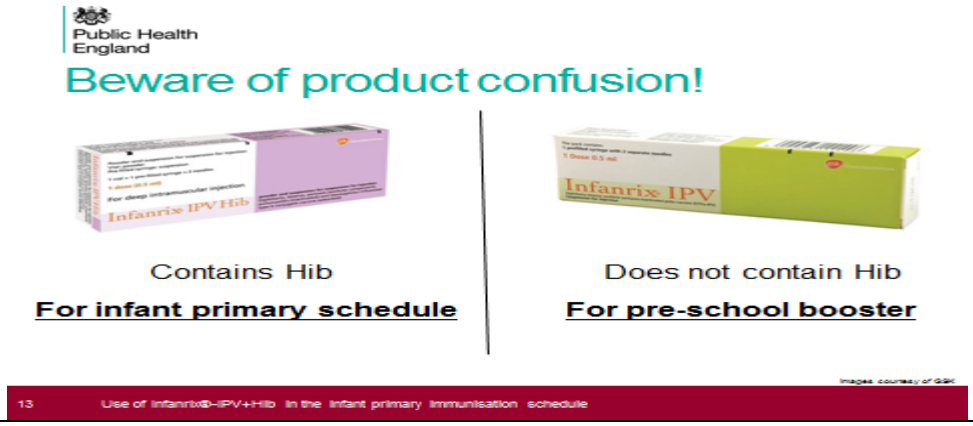
- The health care professional must have a good understanding of the NICE Good Practice Guidance on Patient Group Directions[1]
- The health care professional should undertake the Public Health England training for healthcare practitioners on the Use of infanrix® -IPV +Hib in the infant primary immunisation schedule[2] - accessed via (https://www.gov.uk/government/publications/use-of-infanrix-ipvhib-in-the-infant-immunisation-schedule)
- The NICE competency framework: For health professionals using Patient Group Directions[3] should be used by health care professionals planning to work under this PGD to identify any gaps in their knowledge. The gaps should be addressed before the healthcare professional is authorised to work under this PGD.
- The clinical manager/ lead GP must have evidence that the health care professional has undertaken training to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.
- The healthcare professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.
- The clinical manager/ lead GP must have assessed the competency of the healthcare professional to work to this Patient Group Direction. The NICE competency framework: For health professionals using Patient Group Directions[3] should be used to support this assessment.
- The health care professional must have undertaken training and annual updates in the recognition and treatment of anaphylaxis, including practical in Basic Life Support and has immediate access to an in-date supply of adrenaline 1mg in 1ml (1:1000) at the time of the consultation. (The practitioner must be deemed competent in basic life support and in emergency administration of adrenaline)
- The health care professional must have access to all relevant sources of information e.g. information issued by the Department of Health (Green Book), British National Formulary (BNF), Summary of Product Characteristics (SPC), and the clinical guideline concerning medicine(s) within this Patient Group Direction (PGD).
- The practitioner must be competent and knowledgeable in vaccine cold chain standards.
- The registered health care practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession's Code of Professional Conduct and Ethics.

YOU MUST BE AUTHORISED BY NAME BY YOUR CLINICAL LEAD UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

CLINICAL CONDITION	
Clinical need addressed	For active immunisation against diphtheria, tetanus, pertussis, poliomyelitis and Haemophilus influenzae type b (Hib) in children aged from 2 months and up to 10 years of age as recommended in the routine immunisation schedule[4] NB: Both Infanrix®-IPV+Hib and Pediacel® protect against the same five diseases and so either vaccine can be used in the routine immunisation schedule[2,5], but immunisers must refer to the correct PGD (NB: there is a separate PGD for Pediacel®)
Inclusion criteria	Any child aged from 2 months and up to 10 years of age where parent/guardian consent has been given to receive the vaccine: • As a primary course of diphtheria, tetanus, pertussis, poliomyelitis and Hib in line with routine childhood immunisation schedule or where there is an unreliable history of previous immunisation against diphtheria, tetanus, pertussis, poliomyelitis and Hib • To complete a primary course of diphtheria, tetanus, pertussis, poliomyelitis and Hib
Exclusion criteria (for full details refer to current Summary of Product Characteristics (SPC) www.medicines.org.uk & BNF)	• Consent not given • Child under 2 months of age • Child aged 10 years or over • Acute severe febrile illness (vaccine should be deferred) • Evidence of current neurological deterioration, including poorly controlled epilepsy (defer vaccination) • Less than 4 weeks since receiving diphtheria, tetanus, pertussis, inactivated polio or Hib containing vaccine. • A confirmed anaphylactic reaction to a previous dose of a diphtheria, tetanus, pertussis, polio or Hib-containing vaccine[2,6,7]. • Hypersensitivity to the active substances or to any of the excipients of the vaccine including aluminium hydroxide, neomycin, polymyxin and polysorbate 80 [2,6]
Caution/need for further advice	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[7] As with other vaccines it may be expected that patients receiving immunosuppressive therapy or patients with immunodeficiency, may not achieve an adequate response. In such cases specialist advice should be sought regarding re-immunisation[7]. If a child experiences encephalopathy or encephalitis within 7 days of immunisation, they should be referred to a specialist for investigation. Immunisation should be deferred until the condition has stabilised in children where no underlying cause was found, **and** the child did not recover completely within 7 days. If a cause is identified or the child recovers within 7 days, immunisation should proceed as recommended[7]. The potential risk of apnoea and the need for respiratory monitoring for 48-72h

	should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of the vaccination is high in this group of infants, vaccination should not be withheld or delayed[6].
Interaction with other medicinal products	Vaccine can be given at the same time as other vaccines such as MMR, Men C and hepatitis B. 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 site at which each vaccine was given should be noted in the individual's records [7]
Management of excluded patients	• Document exclusion criteria in the individual's notes. • Advise parent/guardian about reasons for exclusion. • Inform or refer to GP • 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 • For individuals temporarily excluded due to acute or febrile illness advise when the vaccine may be given and arrange another appointment. • For individuals excluded due to evidence of current neurological deterioration, refer to a child specialist for investigation to see if an underlying cause can be identified. If the cause is not identified, immunisation should be deferred until the condition has stabilised. If the cause is identified immunisation should proceed as normal.
Action for patients not wishing to receive care under this PGD	• Advise parent/guardian about protective effects of the vaccine and the risks of infection and disease complications. • Document action and advice given (record declined vaccine in the individuals clinical record). • Inform or refer to GP as appropriate.
TREATMENT AND DRUG DETAILS	
Name form and strength of medicine	**Infanrix®-IPV +Hib (DTaP/IPV/Hib)** Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and Haemophilus type b conjugate vaccine (adsorbed) suspension for injection in pre-filled syringe. **The vaccine is supplied in single dose packs containing the syringe, vial and two needles. One needle for reconstitution and one for vaccine administration.** • The Hib (Haemophilus influenzae type b) vaccine is supplied as a lyophilized (freeze-dried) white powder in a glass vial.[2,5] • The diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine is supplied as a cloudy white suspension in a pre-filled (0.5 ml) syringe.[2,5] **The contents of the pre-filled syringe must be combined with the contents of the vial to make a single dose of 0.5ml of cloudy white suspension [2]**

	
Legal classification	**POM – Prescription Only Medicine**
Black triangle warning Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme (www.yellowcard.gov.uk).	No
Method of obtaining supply	GP practices will be able order online via the ImmForm website (www.immform.dh.gov.uk)
Site for treatment	• GP surgeries
Route/method	**Preparing the Vaccine [2,5,6]** • During storage of the DTaP-IPV suspension, a white deposit and clear fluid above this deposit may be observed in the syringe. This is not a sign of deterioration • The pre-filled syringe should be shaken well • The DTaP-IPV suspension in the pre-filled syringe, the Hib powder in the vial and the reconstituted vaccine should be visually inspected for any foreign particulate matter and/or abnormal physical appearance prior to administration. If either is observed, the vaccine should be discarded • The vaccine is reconstituted by adding the entire contents of the pre-filled syringe of DTaP-IPV suspension to the vial containing the Hib powder • The mixed vaccine should then be injected immediately **The full reconstitution instructions are[2,5]:** 1. Shake the pre-filled syringe containing the DTPa-IPV suspension 2. Attach a green needle to the pre-filled syringe of DTPa-IPV and inject the contents of the syringe into the Hib vial. 3. With the needle still inserted, shake the Hib vial vigorously and examine for complete dissolution. 4. Withdraw the entire mixture back into the syringe. 5. Replace the green needle with an appropriate size needle (blue needle supplied) for injection and administer the vaccine (see below).

6. If the vaccine is not administered immediately, shake the solution vigorously again before injection.

Vaccine Administration

- Infanrix IPV+Hib should be administered by deep intramuscular injection into the anterolateral aspect of the thigh[6]
- It is preferable that each subsequent dose is given into alternating limbs[6].
- Infanrix-IPV+Hib should be administered with caution in patients with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration in these patients. Firm pressure should be applied to the injection site (without rubbing) for at least two minutes[6]. Vaccination by deep subcutaneous route[7] can be considered in patients with bleeding disorders, although there is an increased risk of local reactions via this route[8].
- Vaccine can be given at the same time as other vaccines[5,7]. Preferably in different limbs or at least 2.5cms from the concomitant immunisation[7].

Dose

0.5ml

Number of times treatment may be administered

A primary course consists of three doses to be administered at one month intervals to children aged 2 months, 3 months and 4 months as part of the routine immunisation schedule [4,6]

If the primary course is interrupted it should be resumed but not repeated allowing an interval of a month between remaining doses[2].

Interchangability of Infanrix-IPV+Hib® and Pediacel® vaccines:
Whenever possible the same DTaP containing vaccine should be used for all three doses of the primary vaccine course. If this is not possible, which ever primary vaccine is available (Pediacel® or Infanrix-IPV+Hib® should be used. Vaccination should not be delayed because the vaccine used for the previous dose is unavailable or not known[5]. (NB ensure that the PGD relevant to the vaccine available is used)

Quantity to be supplied or administered

Single dose to be administered (0.5ml)

Side effects

Full details of side effects are available in the SPC.
www.medicines.org.uk
Suspected adverse reactions to drugs including vaccines should be reported on the yellow card available at the back of the BNF. Also at www.yellowcard.gov.uk

Very common: (≥1/10)
Common: (≥ 1/100 to < 1/10)

Adverse Reactions[6]	**Frequency**
Metabolism and Nutrition Disorders	
Appetite loss	Very common
Psychiatric Disorders	
Irritability	Very common
Abnormal crying	Very common
Restlessness	Very Common
Gastrointestinal Disorders	
Vomiting	Common
Diarrhoea	Common
Nervous system disorders	
somnolence	Very common
General Disorders and Administration Site Conditions	
Decreased activity	Very common
Injection site pain	

Injection site redness		
fever (≥38.0°C)		
Injection site swelling (≤50 mm)		
Injection site induration	Common	

For further details about adverse effects see product SPC www.medicines.org.uk

Additional Information (including storage and disposal)	• Store in a refrigerator (+2^{0}C to + 8^{0}C) [2,6] • Do not freeze (If the vaccine has been frozen, the vaccine should be discarded) • Protect from light (store in original packaging) [2,6] • Equipment used for vaccination should be disposed of by placing in a proper, puncture-resistant 'sharps' box according to local authority regulations and guidance in Health Technical Memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)[7]
Advice to patient/carer	**Before Treatment:** • Advise parent/guardian of possible side effects. For full details see product's summary of product characteristics. Advise action to be taken if side effects are experienced **After Treatment:** • Provide information leaflet for parent/guardian • Advise on next scheduled immunisation if appropriate Any serious adverse reaction to the vaccine should be documented in the patient's GP medical records and the MHRA should be informed using the yellow card scheme. GP should also be informed.
Follow up	No routine follow up required
Suspected adverse reactions	Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations. As with all vaccines, healthcare professionals and parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Any serious adverse reaction to the vaccine should be documented in the patient's medical record. .
Error reporting	Any incidents or near-miss issues must be reported to the Screening and Immunisation Team via PHE.sssit@nhs.net
RECORD KEEPING	
Documentation needed/treatment records to be kept for audit purposes *A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.*	• Patient's name, address, date of birth and registered GP • Manufacturer/brand of product, batch number, expiry date • Record of informed consent • Dose administered • Date of administration • Anatomical site of vaccination • Route of administration • Advice given to patient (including advice given if vaccination is declined) • Details of staff who administered (sign and print name)

	• Details of any adverse drug reactions, and action taken including informing GP • Record as supplied via Patient Group Direction (PGD) in patient's clinical record All records should be clear, legible and contemporaneous. This information should be recorded as appropriate in the patient's General Practitioner record or other patient record. A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes. Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday. Data must be stored in accordance with Caldicott guidance and the Data Protection Act. • Reconciliation – stock balances should be reconcilable with receipts, administration records and disposal.

Register of practitioners qualified to administer COMBINED DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS, INACTIVATED POLIO VACCINE AND HIB (DTaP/IPV/Hib – Infanrix® IPV+Hib) under this PATIENT GROUP DIRECTION

Name of clinical manager/GP Lead	
Signature of clinical manager/GP Lead	Date:
A copy of this page should be retained by the authorising manager for 2 years for audit purposes	
Please state clinical area where this PGD is in use	

Healthcare professional individual declaration

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

- **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.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

Name of professional (please print)	Signature	Authorising Manager (Must sign against each entry)	Date of authorisation

The clinical lead should review competency of authorised practitioners annually.

Authorisation to use this PGD does not remove inherent professional responsibility and accountability

Acknowledgement: Medicines Management Team, Telford & Wrekin CCG for developing the PGD.

[1] National Institute for Health and Care Excellence. Good Practice Guidance: Patient Group Directions. August 2013
[2] Public Health England : Use of Infanrix® -IPV+Hib in the infant primary immunisation schedule Training Slides
[3] National Institute for Health and Care Excellence. Competency Framework for healthcare professionals using PGDs. Implementing the NICE good practice guidance on patient group directions (GPG2). Published January 2014
[4] Vaccines for the routine immunisation schedule from summer 2014 The complete routine immunisation schedule
[5] Public Health England. Use of Infanrix® -IPV+Hib in the infant schedule Information for Healthcare Professionals

[6] Summary of Product Characteristics Infanrix ® IPV + Hib www.medicines.org.uk (last accessed August 2014)
[7] Public Health England. Immunisation against infectious disease (The Green Book) Diphtheria, Tetanus, Pertussis, Polio and Hib chapters. Available at: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
[8] Patient Group Direction for the administration of DTaP/IPV/Hib – Infanrix/IPV/Hib. Public Health England/NHS England July 2014