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## PATIENT GROUP DIRECTION (PGD)

Administration of diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis and *Haemophilus influenzae* type b conjugate vaccine (DTaP/IPV/Hib) to individuals from 3 years 4 months to under 10 years of age in accordance with the national immunisation programme for a pre-school booster of DTaP/IPV.

This PGD is for the administration of diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis and *Haemophilus influenzae* type b conjugate vaccine (DTaP/IPV/Hib) by currently registered nurses or paramedics.

Reference no: DTaP/IPV/Hib Booster PGD  
Version no: v01.00  
Valid from: 12 September 2017  
Review date: 01 March 2019  
Expiry date: 31 August 2019

**Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS in line with national recommendations.**

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)<sup>1</sup>. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH [HMR2012 SCHEDULE 16 Part 2](#).**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended.

Operation of this PGD is the responsibility of commissioners and service providers.

**INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from:

<https://www.gov.uk/government/collections/immunisation>

Any concerns regarding the content of this PGD should be addressed to:  
[immunisation@phe.gov.uk](mailto:immunisation@phe.gov.uk)


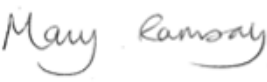

<sup>1</sup> This includes any relevant amendments to legislation (eg [2013 No235](#), [2015 No.178](#) and [2015 No.323](#)).

## Change history

| Version number | Change details   | Date         |
|----------------|--|--------------|
| V01.00         | New DTaP/IPV/Hib Booster PHE PGD Template to allow for reallocation of DTaP/IPV/Hib vaccine stocks to be used for pre-school boosters following the introduction of hexavalent vaccine (DTaP/IPV/Hib/HepB) into the routine infant immunisation programme. | 30 June 2017 |

## 1. PGD template development

This PGD template has been developed by the following health professionals on behalf of Public Health England:

| Developed by:                                   | Name  | Signature  | Date       |
|---|---|--|------------|
| <b>Pharmacist</b><br>(Lead Author)              | Elizabeth Graham<br>Lead Pharmacist Immunisation<br>Services, PHE   |  | 03/07/2017 |
| <b>Doctor</b>                                   | Mary Ramsay<br>Consultant Epidemiologist and Head of<br>Immunisation, Hepatitis & Blood Safety<br>Department, PHE |  | 30/06/2017 |
| <b>Registered Nurse</b><br>(Expert Panel Chair) | David Green<br>Nurse Consultant – Immunisations,<br>PHE   |  | 03/07/2017 |

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Steering Group.

### Expert Panel

| Name                | Designation  |
|---------------------|--|
| Shamez Ladhani      | Paediatric Infectious Disease Consultant, Public Health England  |
| Ed Gardner          | Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead                              |
| Jacqueline Lamberty | Lead Pharmacist Medicines Management Services, Public Health England   |
| Vanessa MacGregor   | Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team                          |
| Alison Mackenzie    | Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)    |
| Sema Mandal         | Medical Consultant Epidemiologist, Public Health England   |
| Gill Marsh          | Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria                       |
| Lesley McFarlane    | Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire                      |
| Sally Millership    | Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team                        |
| Matthew Olley       | Immunisation Manager, Public Health England / NHS England London Region  |
| Lisa Rees           | Medicines Management Pharmacist, Bristol Clinical Commissioning Group  |
| Tushar Shah         | Pharmacy Advisor, NHS England London Region  |
| Kelly Stoker        | Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East                       |
| Sharon Webb         | Programme Manager - Infectious Diseases in Pregnancy Screening (IDPS), NHS Screening Programmes, Public Health England (Midwife) |


## 2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

**NHS ENGLAND MIDLANDS AND EAST (CENTRAL MIDLANDS)** authorises this PGD for use by the services or providers listed below:

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| Authorised for use by the following organisations and/or services  |
| <b>General medical practices from which NHS England Midlands and East (Central Midlands) commissions immunisation services</b> |
| Limitations to authorisation   |
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| Organisational approval (legal requirement)                        |               |  |            |
|--|---------------|--|------------|
| Role   | Name          | Sign   | Date       |
| Medical Director, NHS England Midlands and East (Central Midlands) | Dr Aly Rashid |  | 02.08.2017 |

| Additional signatories according to locally agreed policy |      |      |      |
|---|------|------|------|
| Role  | Name | Sign | Date |
|   |      |      |      |
|   |      |      |      |
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Local enquiries regarding the use of this PGD may be directed to:

For **Bedfordshire, Hertfordshire, Luton and Milton Keynes** - [england.immsqa@nhs.net](mailto:england.immsqa@nhs.net) - the (Central Midlands) South public health/screening and immunisation team

For **Leicestershire, Lincolnshire and Northamptonshire** – [england.limms@nhs.net](mailto:england.limms@nhs.net) - the (Central Midlands) North and Central public health/screening and immunisation team.

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

### 3. Characteristics of staff

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| <p><b>Qualifications and professional registration</b></p> | <p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> <li>• nurses currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• paramedics currently registered with the Health and Care Professions Council (HCPC)</li> </ul>  |
| <p><b>Additional requirements</b></p>                      | <p>Additionally practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it</li> <li>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>• must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using patient group directions)</li> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (“<a href="#">The Green Book</a>”), and national and local immunisation programmes</li> <li>• must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards for Immunisation Training (2005)</a></li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>• must be competent in the handling and storage of vaccines, and management of the “cold chain”</li> <li>• must be competent in the recognition and management of anaphylaxis</li> <li>• must have access to the Patient Group Direction and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul> <p><b>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</b></p> |
| <p><b>Continued training requirements</b></p>              | <p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p>   |

#### 4. Clinical condition or situation to which this PGD applies

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| <p><b>Clinical condition or situation to which this PGD applies</b></p>                     | <p>This PGD supports the use of DTaP/IPV/Hib as an alternative to DTaP/IPV for the pre-school booster to utilise remaining national stocks of pentavalent vaccine following the introduction of hexavalent vaccine (DTaP/IPV/Hib/HepB) into the routine childhood immunisation schedule.</p> <p>Indicated for the active immunisation of individuals from 3 years 4 months to under 10 years of age for the prevention of diphtheria, tetanus, pertussis and poliomyelitis, in accordance with the national immunisation programme and recommendations given in <a href="#">Chapter 15</a>, <a href="#">Chapter 24</a>, <a href="#">Chapter 26</a> and <a href="#">Chapter 30</a> of Immunisation Against Infectious Disease: “The Green Book”.</p>  |
| <p><b>Criteria for inclusion</b></p>  | <p>Individuals from 3 years 4 months to under 10 years of age who:</p> <ul style="list-style-type: none"> <li>• require a booster following a primary course of immunisation against diphtheria, tetanus, pertussis and poliomyelitis (this booster is usually offered from 3 years 4 months of age)</li> <li>• have a tetanus prone wound and tetanus boosters are not up to date or are due soon and convenient to give now (See “The Green Book” <a href="#">Chapter 30</a>)</li> </ul>   |
| <p><b>Criteria for exclusion<sup>2</sup></b></p>  | <p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are less than 3 years 4 months of age</li> <li>• are aged 10 years and over</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis, poliomyelitis or <i>Haemophilus influenzae</i> type b containing vaccine, including any conjugate vaccines where diphtheria or tetanus toxoid is used in the conjugate</li> <li>• have had a confirmed anaphylactic reaction to any component of the vaccine or residual products from manufacture, these may include neomycin, polymyxin, polysorbate 80, streptomycin, glutaraldehyde, formaldehyde and bovine serum albumin (refer to relevant SPC)</li> <li>• have not yet completed primary immunisation with three doses of diphtheria, tetanus, pertussis and poliomyelitis antigen</li> <li>• received a dose of diphtheria, tetanus, pertussis and poliomyelitis containing vaccine within the last 12 months</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> </ul> |
| <p><b>Cautions including any relevant action to be taken</b></p> <p>Continued over page</p> | <p>The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.</p>  |

<sup>2</sup> Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

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| <p><b>Cautions including any relevant action to be taken</b><br/>(continued)</p> | <p>If a child has experienced encephalopathy or encephalitis within seven days of immunisation, it is unlikely that these conditions will have been caused by the vaccine and they should be investigated by a specialist. If a cause is identified or the child recovered within seven days, immunisation should proceed as recommended. In children where no underlying cause was found and the child did not recover completely within seven days, immunisation should be deferred until the condition has stabilized or the expected course of the condition becomes clear.</p> <p>If a seizure associated with a fever occurred within 72 hours of a previous immunisation with pertussis containing vaccine, immunisation should continue as recommended if a cause is identified or the child recovers within 24 hours. However, if no underlying cause has been found and the child did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable.</p> <p>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate.</p>   |
| <p><b>Action to be taken if the patient is excluded</b></p>                      | <p>If the individual is aged less than 3 years 4 months assess for immunisation with DTaP/IPV/Hib/HepB or DTaP/IPV/Hib (see DTaP/IPV/Hib/HepB PGD and DTaP/IPV/Hib PGD for the primary immunisation series).</p> <p>If the individual is aged 10 years or over assess for immunisation with Td/IPV as required.</p> <p>If the individual has not yet completed primary immunisation with three doses of diphtheria, tetanus, pertussis and poliomyelitis antigen provide priming doses of DTaP/IPV/Hib/HepB, DTaP/IPV/Hib or DTaP/IPV as required. Note: this is outside the remit of this PGD.</p> <p>If a dose of diphtheria, tetanus, pertussis and poliomyelitis containing vaccine has been received within the last 12 months, defer immunisation until appropriate interval.</p> <p>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required rather than delay immunisation.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document reason for exclusion and any action taken in the individual's clinical records.</p> <p>In a GP practice setting, inform or refer to the GP or prescriber as appropriate.</p> |

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| <p><b>Action to be taken if the patient or carer declines treatment</b></p> | <p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration.</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.</p> <p>Document advice given and the decision reached.</p> <p>In a GP practice setting, inform or refer to the GP as appropriate.</p> |
| <p><b>Arrangements for referral for medical advice</b></p>                  | <p>As per local policy</p>   |

## 5. Description of treatment

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| <b>Name, strength &amp; formulation of drug</b>                    | <p>Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and <i>Haemophilus influenzae</i> type b conjugate vaccine (adsorbed), DTaP/IPV/Hib, eg:</p> <ul style="list-style-type: none"> <li>• Infanrix<sup>®</sup>-IPV+Hib, powder (Hib) in vial and suspension (DTaP/IPV) for suspension for injection in pre-filled syringe</li> <li>• Pediacel<sup>®</sup>, suspension for injection in pre-filled syringe</li> </ul>   |
| <b>Legal category</b>  | <p>Prescription only medicine (POM)</p>  |
| <b>Black triangle ▼</b>  | <p>No</p>  |
| <b>Off-label use</b>   | <p>Administration of Infanrix<sup>®</sup>-IPV+Hib to individuals over 3 years of age and Pediacel<sup>®</sup> to individuals aged 4 years and over is off-label but is indicated until 10 years of age under this PGD in accordance with PHE recommendations for the <a href="#">vaccination of individuals with uncertain or incomplete immunisation status</a>, the relevant chapters of “<a href="#">The Green Book</a>” and <a href="#">The hexavalent DTaP/IPV/Hib/HepB combination vaccine information for healthcare professionals</a>.</p> <p>Administration of DTaP/IPV/Hib to individuals who experienced an encephalopathy of unknown cause occurring within 7 days following previous vaccination with pertussis containing vaccine is off-label. Individuals may be vaccinated under this PGD once the condition has stabilized or the expected course of the condition becomes clear (see <a href="#">Cautions</a>), in line with the recommendations in the associated chapters of “<a href="#">The Green Book</a>”.</p> <p>Administration by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in <a href="#">Chapter 4</a> of “<a href="#">The Green Book</a>”.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p> |
| <b>Route / method of administration</b><br><br>Continued over page | <p>Some vaccine products (eg Infanrix<sup>®</sup>-IPV+Hib) must be reconstituted in accordance with the manufacturers’ instructions prior to administration.</p> <p>Administer by intramuscular injection, preferably into deltoid region of the upper arm.</p> <p>When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. 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.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see “<a href="#">The Green Book</a>” <a href="#">Chapter 4</a>).</p> <p>The vaccine's normal appearance is a uniform cloudy, white suspension which may sediment during storage. Shake the pre-filled syringe well to uniformly distribute the suspension prior to</p>  |

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| <b>Route / method of administration</b><br>(continued) | reconstitution (if applicable) and before administering the vaccine.<br>The vaccine should be inspected prior to and after any required reconstitution and should not be used if discoloured or foreign particles are present.<br>The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>  |
| <b>Dose and frequency of administration</b>            | Single 0.5ml dose per administration<br><b>Routine Childhood Immunisation Schedule</b><br>Diphtheria, tetanus, pertussis and polio containing vaccine should ideally be given three years after completion of the primary course of diphtheria, tetanus, pertussis and polio vaccination as the first booster dose and is recommended as a pre-school vaccine at around 3 years and 4 months of age though it may be used until 10 years of age.<br>When primary vaccination has been delayed, this first booster dose may be given at the scheduled visit provided it is at least 12 months since the last primary dose was administered.<br>Where children have had a fourth dose of tetanus, diphtheria and polio containing vaccine at around 18 months of age, this dose should be discounted as it may not provide satisfactory protection until the time of the teenage booster. The routine pre-school and subsequent boosters should be given according to the UK schedule.<br><b>Management of tetanus prone wound</b><br>Individuals with incomplete or uncertain history of tetanus immunisation should be vaccinated in accordance with the recommendations in the "The Green Book" <a href="#">Chapter 30</a> Table 30.1.<br>Individuals may also require human tetanus immunoglobulin (see "The Green Book" <a href="#">Chapter 30</a> ). |
| <b>Duration of treatment</b>                           | <b>Routine Immunisation</b><br>A single dose as pre-school booster.<br>See other PGDs for primary immunisation (DTaP/IPV/Hib/HepB or DTaP/IPV/Hib) and subsequent boosters (Td/IPV) to complete immunisation in accordance with national recommendations.  |
| <b>Quantity to be supplied / administered</b>          | Single 0.5ml dose per administration.  |
| <b>Supplies</b>  | Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge.<br>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see <a href="#">protocol for ordering storage and handling of vaccines</a> and Green Book <a href="#">Chapter 3</a> ).  |
| <b>Storage</b>   | Store at +2°C to +8°C.<br>Store in original packaging in order to protect from light.<br>Do not freeze.  |

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| <b>Disposal</b>   | <p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the <a href="#">technical memorandum 07-01</a>: Safe management of healthcare waste (Department of Health, 2013).</p>  |
| <b>Drug interactions</b>  | <p>Immunological response may be diminished in those receiving immunosuppressive treatment.</p> <p>May be given at the same time as other vaccines.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>  |
| <b>Identification &amp; management of adverse reactions</b>                       | <p>Local reactions following vaccination are very common ie pain, swelling or redness at the injection site. A small painless nodule may form at the injection site.</p> <p>Common adverse reactions include fever, abnormal crying, irritability, restlessness, diarrhoea, vomiting, appetite loss, somnolence, decreased activity and injection site bruising.</p> <p>Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions is available in the vaccine's Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p> |
| <b>Reporting procedure of adverse reactions</b>                                   | <p>As with all vaccines, healthcare professionals and patients/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: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p>  |
| <b>Written information to be given to patient or carer</b>                        | <p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> <li>• <a href="#">Pre-school immunisations: guide to vaccinations (2 to 5 years)</a></li> </ul> <p>Available from: <a href="http://www.gov.uk/government/collections/immunisation">www.gov.uk/government/collections/immunisation</a></p>  |
| <b>Patient advice / follow up treatment</b>                                       | <p>Inform the individual/carer of possible side effects and their management.</p> <p>The individual/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>When administration is postponed advise the individual/carer when to return for vaccination.</p>   |
| <b>Special considerations / additional information</b><br><br>Continued over page | <p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.</p> <p>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell,</p>  |

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| <p><b>Special considerations / additional information</b><br/>(continued)</p> | <p>immunisation may be postponed until they have fully recovered.</p> <p>Tetanus vaccine given at the time of a tetanus-prone injury may not boost immunity early enough to give additional protection within the incubation period of tetanus. Therefore, tetanus vaccine is not considered adequate for treating a tetanus-prone wound. However, this provides an opportunity to ensure that the individual is protected against future exposure. Individuals may also require human tetanus immunoglobulin (see “The Green Book” <a href="#">Chapter 30</a>).</p> <p>If a person has received vaccination for a tetanus-prone wound with the same vaccine as due for routine immunisation or booster and was administered at an appropriate interval then the routine booster dose is not required, refer to advice in “The Green Book” <a href="#">Chapter 30</a>.</p>  |
| <p><b>Records</b></p>   | <p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given</li> <li>• name of individual, address, date of birth and GP with whom the individual is registered</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled immuniser’s record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the individual’s GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual’s GP informed.</p> <p>The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway when vaccine is administered to individuals under 19 years of age.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p> |

## 6. Key references

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| <b>Key references</b> | <p><b>DTaP/IPV/Hib vaccine</b></p> <ul style="list-style-type: none"><li>• Immunisation Against Infectious Disease: The Green Book <a href="#">Chapter 15</a>, <a href="#">Chapter 16</a>, <a href="#">Chapter 26</a> and <a href="#">Chapter 30</a>. Last updated 19 April 2013. <a href="#">Chapter 24</a>. Last updated 7 April 2017<br/><a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li><li>• Summary of Product Characteristic for Infanrix<sup>®</sup>-IPV+Hib, GlaxoSmithKline. 25 April 2017.<br/><a href="http://www.medicines.org.uk/emc/medicine/28678">http://www.medicines.org.uk/emc/medicine/28678</a></li><li>• Summary of Product Characteristic for Pediacel<sup>®</sup>, Sanofi Pasteur. 15 March 2017. <a href="http://www.medicines.org.uk/emc/medicine/26217">http://www.medicines.org.uk/emc/medicine/26217</a></li><li>• NHS public health functions agreement 2017-18, Service Specification No.9. DTaP/IPV and dTaP/IPV pre-school booster immunisation programme. April 2017.<br/><a href="https://www.england.nhs.uk/wp-content/uploads/2017/04/service-spec-09.pdf">https://www.england.nhs.uk/wp-content/uploads/2017/04/service-spec-09.pdf</a></li><li>• The hexavalent DTaP/IPV/Hib/HepB combination vaccine information for healthcare practitioners<br/><a href="https://www.gov.uk/government/publications/hexavalent-combination-vaccine-programme-guidance">https://www.gov.uk/government/publications/hexavalent-combination-vaccine-programme-guidance</a></li><li>• Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 20 June 2016.<br/><a href="https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status">https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• PHE Immunisation Collection<br/><a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• British National Formulary (BNF) and British National Formulary for Children (BNF-C) <a href="http://www.BNF.org">www.BNF.org</a><br/><a href="https://www.evidence.nhs.uk/formulary/bnf/current">https://www.evidence.nhs.uk/formulary/bnf/current</a></li><li>• National Minimum Standards for Immunisation Training (2005)<br/><a href="https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards">https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017.<br/><a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014.<br/><a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li><li>• Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015.<br/><a href="https://www.rcn.org.uk/professional-development/publications/pub-005336">https://www.rcn.org.uk/professional-development/publications/pub-005336</a></li><li>• Protocol for ordering storage and handling of vaccines. April 2014.<br/><a href="https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines">https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines</a></li><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013<br/><a href="https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste">https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste</a></li></ul> |
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## 7. Practitioner authorisation sheet

**DTaP/IPV/Hib Booster PGD v01.00 Valid from: 12/09/2017 Expiry: 31/08/2019**

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

### Practitioner

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

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
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|      |             |           |      |

### Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of \_\_\_\_\_ (insert name of practice) for the above named health care professionals who have signed the PGD to work under it.

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
|      |             |           |      |

### Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.