



PHE publications gateway number: GW-875

## Diphtheria, Tetanus, Acellular Pertussis and Inactivated Poliomyelitis Vaccine Patient Group Direction (PGD)

This PGD is for the administration of diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV) to individuals from 3 years 4 months to under 10 years of age, in accordance with the national immunisation programme, or for the management of cases and contacts of diphtheria, tetanus, pertussis or poliomyelitis from 3 years of age.

This PGD is for the administration of diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV) by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no: dTaP/IPV PGD  
Version no: v03.00  
Valid from: 1 December 2019  
Review date: 1 June 2021  
Expiry date: 30 November 2021

**Public Health England has developed this PGD to facilitate publicly-funded immunisation 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 the 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 within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

**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-patient-group-direction-pgd>

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 (such as [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).  
dTAP/IPV PGD v03.00 Valid from: 01/12/2019 Expiry: 30/11/2021

## Change history

Version number	Change details	Date
V01.00	New PHE PGD template	15 December 2015
V02.00	DTaP/IPV PGD routine review and amended to: <ul style="list-style-type: none"> <li>• include vaccination in line with recommendations for the management of diphtheria or polio</li> <li>• remove exclusions regarding timing of previous vaccination (see dose section for schedules)</li> <li>• remove exclusions relating to neurological conditions and encephalopathy and relevant advice moved to the cautions section</li> <li>• update off-label section in relation to amended exclusions</li> <li>• update dose section with management of cases and contacts of polio and diphtheria</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	29 September 2017
V03.00	dTaP/IPV PGD routine review and amended to: <ul style="list-style-type: none"> <li>• removed the DTaP/IPV (Infanrix®-IPV) product as not currently marketed in the UK</li> <li>• include Boostrix®-IPV</li> <li>• include individuals identified by an Outbreak Control Team for immunisation in response to a school/nursery pertussis outbreak</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs</li> </ul>	22 October 2019

## 1. PGD development

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

Developed by:	Name	Signature	Date
<b>Pharmacist</b> (Lead Author)	Elizabeth Graham Lead Pharmacist, Immunisation and Countermeasures, PHE		22/10/2019
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		25/10/2019
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		23/10/2019

This PGD 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 Delivery Board.

## Expert Panel

Name	Designation
Gayatri Amirthalingam	Consultant Epidemiologist, 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
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
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 (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Co-ordinator, Public Health England / NHS England and NHS Improvement Leicestershire, Lincolnshire and Northamptonshire
Tushar Shah	Pharmacy Advisor, NHS England London Region
Sharon Webb	Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England


## 2. Organisational authorisations



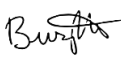
The PGD is not legally valid until it has had the relevant organisational authorisation.

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 and NHS Improvement East of England** authorises this PGD for use by the services or providers listed below:

<b>Authorised for use by the following organisations and/or services</b>
All NHS England and NHS Improvement East of England commissioned immunisation services or NHS Trust providing immunisation services covering Norfolk, Suffolk, Cambridgeshire, Peterborough, Essex, Southend-on-Sea, Thurrock, Bedfordshire, Hertfordshire, Luton and Milton Keynes local authorities, and Health and Justice facilities where NHS England and NHS Improvement East of England is the commissioner.
<b>Limitations to authorisation</b>
None

<b>Organisational approval (legal requirement)</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
<b>Associate Medical Director</b>	<b>Dr. James Hickling</b>		<b>18/11/2019</b>

<b>Additional signatories according to locally agreed policy</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
<b>Screening and Immunisation Lead</b>	<b>Dr. Pam Hall</b>		<b>12/11/2019</b>
<b>Pharmacist</b>	<b>Dr. Paul Duell</b>		<b>11/11/2019</b>
<b>Screening and Immunisation Coordinator</b>	<b>Alex Burghlea</b>		<b>08/11/2019</b>

Local enquiries regarding the use of this PGD may be directed to

For East Anglia email: [England.ea-phsi@nhs.net](mailto:England.ea-phsi@nhs.net)

For Essex email: [England.essexatimms@nhs.net](mailto:England.essexatimms@nhs.net)

For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: [England.immsga@nhs.net](mailto:England.immsga@nhs.net)

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

<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 and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>• paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below.</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<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 PGD 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 PGDs)</li> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the '<a href="#">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 and Core Curriculum for Immunisation Training</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 PGD 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

<p><b>Clinical condition or situation to which this PGD applies</b></p>	<p>Indicated for the active immunisation of individuals from 3 years 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' and associated disease management guidelines (see <a href="#">Dose and frequency of administration</a> section)</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> </ul> <p>Individuals from 3 years of age (see <a href="#">Additional information</a> regarding individuals over 10 years) who:</p> <ul style="list-style-type: none"> <li>• have a tetanus-prone wound and tetanus immunisation is recommended in accordance with PHE Tetanus <a href="#">Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds</a> or tetanus boosters are due soon and it is convenient to give now (see the 'Green Book' <a href="#">Chapter 30</a>)</li> <li>• require vaccination in line with recommendations for the management of cases and contacts of diphtheria or polio</li> <li>• are identified by an Outbreak Control Team for immunisation in response to a school/nursery pertussis outbreak, in accordance with the PHE <a href="#">Guidelines for the Public Health Management of Pertussis in England</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>• have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis or poliomyelitis 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 formaldehyde, glutaraldehyde, streptomycin, neomycin, polymyxin and bovine serum albumin (refer to relevant <a href="#">SPC</a>)</li> <li>• have not yet completed primary immunisation with three doses of diphtheria, tetanus, pertussis and poliomyelitis antigen unless recommended by an Outbreak Control Team</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>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 was identified, or the child recovered within 24 hours. However, if no underlying cause was found and the child did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable.</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> (continued)</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> <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>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>Individuals who are immunosuppressed may not be adequately protected against tetanus, despite having been fully immunised. In the event of an exposure they may require additional boosting and/or immunoglobulin (see the 'Green Book' <a href="#">Chapter 30</a> and PHE Tetanus <a href="#">Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds</a>).</p>
<p><b>Action to be taken if the patient is excluded</b></p>	<p>Individuals who have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis and poliomyelitis vaccine, or any components of the vaccine, should be referred to a clinician for specialist advice and appropriate management.</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 as required (see DTaP/IPV/Hib/HepB PGD).</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, Outbreak Control Team or the individual's clinician where appropriate.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>Inform, or refer to, the GP or a prescriber as appropriate.</p>

<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.</p> <p>Document advice given, and the decision reached.</p> <p>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

<b>Name, strength &amp; formulation of drug</b>	<p>Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed):</p> <ul style="list-style-type: none"> <li>• Repevax<sup>®</sup>, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV</li> <li>• Boostrix<sup>®</sup>-IPV, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV</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 Boostrix<sup>®</sup>-IPV by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration but may be considered where this remains in line with advice in <a href="#">Chapter 4</a> of the 'Green Book'. Alternatively, firm pressure should be applied to the injection site (without rubbing) for at least two minutes in accordance with the recommendations in the product's <a href="#">SPC</a>. Note: The Repevax<sup>®</sup> SPC includes consideration of administration by deep subcutaneous injection to individuals with bleeding disorders.</p> <p>Administration to individuals who have experienced an encephalopathy of unknown origin within 7 days of previous vaccination with a pertussis-containing vaccine is off-label but may proceed once the cause is identified or the condition has been stabilized in accordance with the recommendations in <a href="#">Chapter 24</a> of Immunisation Against Infectious Disease: the 'Green Book'.</p> <p>The vaccine product SPCs do not make reference to use of dTaP/IPV for the management of outbreak, cases or contacts but do include use of the vaccine as a booster and state that the vaccine should be administered in accordance with official recommendations. Vaccination is therefore recommended under this PGD in accordance with the relevant chapters of the Green Book and associated PHE guidelines (see <a href="#">Dose and frequency of administration</a>).</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage</a> section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">PHE Vaccine Incident Guidance</a>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</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>  Continued over page	<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><b>Route / method of administration</b> continued</p>	<p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the 'Green Book' <a href="#">Chapter 4</a> or the product's <a href="#">SPC</a> (see <a href="#">Off-label use</a> section).</p> <p>The vaccine's normal appearance is a uniform cloudy, white suspension which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine.</p> <p>The vaccine should not be used if discoloured or foreign particles are present in the suspension.</p> <p>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></p>
<p><b>Dose and frequency of administration</b></p> <p>Continued over page</p>	<p>Single 0.5ml dose per administration</p> <p><b>Routine childhood immunisation schedule</b></p> <p>The dTaP/IPV booster 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.</p> <p>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.</p> <p>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. Additional doses of DTaP-containing vaccines given under 3 years of age do not count as a booster to the primary course in the UK. The routine pre-school and subsequent boosters should be given according to the UK schedule.</p> <p><b>Management of tetanus prone wound</b></p> <p>Individuals with incomplete or uncertain history of tetanus immunisation should be vaccinated in accordance with the recommendations in the 'Green Book' <a href="#">Chapter 30</a> Table 30.1 and PHE Tetanus <a href="#">Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds</a>.</p> <p>In accordance with those recommendations, individuals who are immunosuppressed may require additional boosting.</p> <p>Individuals may also require human tetanus immunoglobulin. Administration of tetanus immunoglobulin is not covered by this PGD.</p> <p><b>Management of cases and contacts of diphtheria</b></p> <p>Cases and contacts of diphtheria should be managed in accordance with <a href="#">Public health control and management of diphtheria (in England and Wales) guidelines</a> and recommendations from the local health protection team.</p>

<p><b>Dose and frequency of administration</b> continued</p>	<p>Individuals who are fully immunised but have not received diphtheria containing vaccine in last 12 month may be given a single booster dose of diphtheria containing vaccine.</p> <p><b>Management of pertussis outbreak in a school/nursery</b></p> <p>Cases and contacts of pertussis in a school/nursery outbreak should be managed in accordance with PHE <a href="#">Guidelines for the Public Health Management of Pertussis in England</a> and recommendations from the Outbreak Control Team.</p> <p><b>Management of cases and contacts of polio</b></p> <p>Cases and contacts of polio should be managed in accordance with <a href="#">PHE national polio guidelines: Local and regional services</a> guidelines and recommendations from the local health protection team.</p> <p>Management will depend on the level of exposure but may include the administration of a single dose of IPV containing vaccine, regardless of vaccine history.</p>
<p><b>Duration of treatment</b></p>	<p>A single booster dose.</p> <p>Other diphtheria, tetanus, pertussis and polio vaccines are recommended for primary immunisation (that is DTaP/IPV/Hib/HepB) and subsequent boosters (that is the Td/IPV adolescent booster) to complete immunisation in accordance with national recommendations.</p>
<p><b>Quantity to be supplied / administered</b></p>	<p>Single 0.5ml dose per administration.</p>
<p><b>Supplies</b></p>	<p>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.</p> <p>Vaccine for indications other than the national immunisation programme should be obtained from manufacturers/wholesalers.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' <a href="#">Chapter 3</a>).</p>
<p><b>Storage</b></p>	<p>Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal, refer to <a href="#">PHE Vaccine Incident Guidance</a>.</p>
<p><b>Disposal</b></p>	<p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely 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. Vaccination is recommended even if the antibody response may be limited.</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 such as 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, irritability, headache, nausea, diarrhoea, vomiting, rash, arthralgia, appetite loss, malaise, fatigue/asthenia, dermatitis, bruising and pruritus.</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 SPC, 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>Healthcare professionals and individuals/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="http://www.gov.uk/government/collections/immunisation">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/parent of possible side effects and their management.</p> <p>The individual/carer/parent should be advised to seek medical advice in the event of an adverse reaction.</p> <p>When administration is postponed advise the individual/carer/parent when to return for vaccination.</p>
<b>Special considerations / additional information</b>	<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>Individuals should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes.</p> <p>The dTaP/IPV (Repevax<sup>®</sup> or Boostrix<sup>®</sup>-IPV) vaccine contains a lower dose of pertussis antigen, as well as a lower dose of diphtheria antigen, compared to DTaP/IPV (Infanrix<sup>®</sup>-IPV) or DTaP/IPV/Hib/HepB. It is important that primary vaccination in children is undertaken using a product with higher doses of pertussis, diphtheria and tetanus antigens (currently that is</p>

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<p><b>Special considerations / additional information</b> continued</p>	<p>DTaP/IPV/Hib/HepB) to ensure that adequate priming occurs. Therefore, individuals immunised as part of an outbreak response but who have not completed primary immunisation should be referred to their GP for immunisation in accordance with <a href="#">Vaccination of individuals with uncertain or incomplete immunisation status</a> algorithm. Where a dTaP/IPV vaccine has been administered to an individual who has not completed primary immunisation the dose of dTaP/IPV should be discounted.</p> <p>Individuals over 10 years of age should preferably be vaccinated using Td/IPV (Revaxis®) where protection against pertussis is not required. However, dTaP/IPV may be offered to individuals with a tetanus prone wound and cases or contacts of diphtheria or polio where Td/IPV (Revaxis®) is either not available or dTaP/IPV is recommended for a cohort identified by an Outbreak Control Team.</p> <p>Pertussis vaccination may be recommended for individuals over 10 years of age under inclusion criteria not covered by this PGD (see PHE Pertussis PGD).</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, or as a case or contact of diphtheria, tetanus or polio, with the same vaccine as due for routine immunisation and it was administered at an appropriate interval then the routine immunisation dose may not be required.</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 vaccinator</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 vaccination</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via PGD</li> </ul> <p>Records should be signed and dated (or a password-controlled vaccinator'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</p>

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<b>Records</b> (continued)	documentation/pathway as required by any local or contractual arrangement.  A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.
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## 6. Key references

<b>Key references</b>	<p><b>The dTaP/IPV 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 26</a> updated 19 April 2013, <a href="#">Chapter 30</a> updated 26 November 2018 and <a href="#">Chapter 24</a> updated 7 April 2016 <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 Repevax<sup>®</sup>, Sanofi Pasteur. 7 April 2019. <a href="http://www.medicines.org.uk/emc/medicine/15256">http://www.medicines.org.uk/emc/medicine/15256</a></li><li>• Summary of Product Characteristic for Boostrix<sup>®</sup>-~IPV, GlaxoSmithKline UK. 2 January 2019. <a href="https://www.medicines.org.uk/emc/product/5302">https://www.medicines.org.uk/emc/product/5302</a></li><li>• NHS public health functions agreement 2018-19, Service Specification No.9. DTaP/IPV and dTaP/IPV pre-school booster immunisation programme. September 2018. <a href="https://www.england.nhs.uk/publication/public-health-national-service-specifications/">https://www.england.nhs.uk/publication/public-health-national-service-specifications/</a></li><li>• Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 22 August 2019. <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><li>• Public health control and management of diphtheria (in England and Wales) guidelines. Public Health England. 24 March 2015. <a href="https://www.gov.uk/government/publications/diphtheria-public-health-control-and-management-in-england-and-wales">https://www.gov.uk/government/publications/diphtheria-public-health-control-and-management-in-england-and-wales</a></li><li>• Guidelines for the Public Health Management of Pertussis in England. Published May 2018. <a href="https://www.gov.uk/government/publications/pertussis-guidelines-for-public-health-management">https://www.gov.uk/government/publications/pertussis-guidelines-for-public-health-management</a></li><li>• PHE national polio guidelines: Local and regional services. Public Health England. 26 September 2019. <a href="https://www.gov.uk/government/publications/polio-national-guidelines">https://www.gov.uk/government/publications/polio-national-guidelines</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. <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><li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. <a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <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. Updated March 2017.</li></ul>
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<b>Key references</b> continued	<p><a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></p> <ul style="list-style-type: none"><li>• PHE Immunisation Collection <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• PHE Vaccine Incident Guidance <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li></ul>
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## 7. Practitioner authorisation sheet

**DTaP/IPV PGD v03.00 Valid from: 01/12/2019 Expiry: 30/11/2021**

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

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to 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 PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

### 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 <b>INSERT NAME OF ORGANISATION:</b>  for the named healthcare professionals above 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.