



## PATIENT GROUP DIRECTION (PGD)

Administration of low dose diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV) to women from 16 weeks of pregnancy in accordance with the pertussis vaccination for pregnant women national immunisation programme and to contacts of pertussis, from 10 years of age, in accordance with PHE Guidelines for the Public Health Management of Pertussis in England and/or PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings.

This PGD is for the administration of low dose 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: Pertussis PGD  
Version no: 04.00  
Valid from: 01 April 2019  
Review date: 1 October 2020  
Expiry date: 31 March 2021

**Public Health England has developed this PGD to facilitate the delivery of 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.

**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 (eg [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).

## Change history

Version number	Change details	Date
V01.00	New PHE PGD template	15 December 2015
V02.00	Vaccine eligibility changed from 'from 28 weeks of pregnancy' to 'from 20 weeks of pregnancy'.	24 March 2016
V03.00	<p>PHE Pertussis PGD amended to:</p> <ul style="list-style-type: none"> <li>• reflect service specification for vaccine eligibility 'from 16 weeks of pregnancy' rather than 'from 20 weeks of pregnancy'</li> <li>• reference the protocol for ordering storage and handling of vaccines</li> <li>• update wording regarding authorisation in line with agreed PHE PGD template changes and multiple practitioner authorisation sheet,</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	24 March 2017
V04.00	<p>PHE Pertussis PGD amended to:</p> <ul style="list-style-type: none"> <li>• include additional healthcare practitioners in Section 3, including radiographers to allow for potential commissioning arrangements for immunisation at the time of the fetal anomaly scan</li> <li>• include immunisation of contacts of pertussis in accordance with PHE guidelines</li> <li>• remove the off-label status for use in pregnancy</li> <li>• include additional stability statement for Boostrix-IPV in the storage section</li> <li>• refer to vaccine incident guidelines in off-label and storage sections</li> <li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates</li> </ul>	11 January 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		24/01/2019
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		24/01/2019
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant – Immunisation and Countermeasures, PHE		24/01/2019

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
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)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator, NHS England / Public Health England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Tushar Shah	Pharmacy Advisor, NHS England London Region
Sharon Webb	Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Principal Pharmacist, Bristol, North Somerset & South Gloucestershire Clinical Commissioning Group


## 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 Cheshire and Merseyside authorises this PGD for use by the services or providers listed below:

<b>Authorised for use by the following organisations and/or services</b>
Immunisation services in Cheshire and Merseyside commissioned by NHS England.
<b>Limitations to authorisation</b>
Use of this PGD by organisations which are <b>not</b> commissioned to provide the services described above

<b>Organisational approval (legal requirement)</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
Medical Director, NHSE North (Cheshire and Merseyside) and (Lancashire and South Cumbria)	<b>Kieran Murphy</b>		<b>18/02/2019</b>

<b>Additional signatories according to locally agreed policy</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>

Local enquiries regarding the use of this PGD may be directed to the following email address:

Cheshire and Merseyside Screening and immunisation team: [England.cm-imms@nhs.net](mailto:England.cm-imms@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, physiotherapists and radiographers 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 products and alert to changes in their 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 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 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 immunisation of women from 16 weeks of pregnancy in accordance with the recommendations given in <a href="#">Chapter 24</a> of Immunisation Against Infectious Disease: 'The Green Book' and for the immunisation of contacts of pertussis, from 10 years of age, in accordance with <a href="#">Guidelines for the Public Health Management of Pertussis in England</a> or <a href="#">PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings</a></p>
<p><b>Criteria for inclusion</b></p>	<p>Pregnant women from 16 weeks<sup>2</sup> of pregnancy.</p> <p>Mothers with an infant less than 2 months of age who did not receive pertussis vaccination during their pregnancy.</p> <p>Contacts of pertussis, from 10 years of age, recommended pertussis vaccination in accordance with <a href="#">Guidelines for the Public Health Management of Pertussis in England</a> or <a href="#">PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings</a></p>
<p><b>Criteria for exclusion<sup>3</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 16 weeks pregnant (with the exception of post-exposure vaccination, at any stage of pregnancy, of contacts at risk of transmitting pertussis to 'vulnerable' individuals)</li> <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 SPC)</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>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with the national recommendations.</p> <p>Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p>

<sup>2</sup> From 16 weeks of pregnancy means a gestation of 16 weeks plus 0 days (16<sup>+0</sup>) or more.

<sup>3</sup> Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

<p><b>Action to be taken if the patient is excluded</b></p>	<p>If less than 16 weeks of pregnancy delay vaccination until indicated unless post-exposure vaccination is indicated in accordance with <a href="#">Guidelines for the Public Health Management of Pertussis in England</a> or <a href="#">PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings</a>.</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, the local Health Protection 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>In a GP practice setting, 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>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>

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## 5. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	<p>Low dose diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed), eg:</p> <ul style="list-style-type: none"> <li>• Boostrix®-IPV, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV</li> <li>• Repevax®, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV – see <a href="#">Supplies</a> section.</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®-IPV by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in <a href="#">Chapter 4</a> and <a href="#">Chapter 24</a> of 'The Green Book'.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage section</a> 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/patient/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>	<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 'The Green Book' <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 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>Single 0.5ml dose per administration</p> <p><b>Routine immunisation in pregnancy schedule</b></p> <p>A single dose of dTaP/IPV should ideally be administered between 16 weeks and 32 weeks of pregnancy to maximise the likelihood that the baby will be protected from birth. For operational reasons, vaccination is best offered on or after the fetal anomaly scan at around 20 weeks.</p> <p>Women may still be immunised after week 32 of pregnancy but this may not offer as high a level of passive protection to the baby. Vaccination late in pregnancy may, however, directly protect the mother against disease and thereby reduce the risk of exposure to her infant.</p> <p>This vaccine should be offered regardless of prior vaccination status. Vaccination is indicated in each pregnancy.</p> <p>For women who have not received the vaccine in pregnancy, pertussis-containing vaccine can be offered to mothers in the two months following birth ie up until their child receives their first dose of pertussis containing vaccine, to reduce the risk of the mother contracting pertussis in the post-partum period and therefore prevent her from infecting her infant.</p> <p><b>Public health management of pertussis</b></p> <p>A single dose of dTaP/IPV should be administered to contacts recommended immunisation in accordance with <a href="#">Guidelines for the Public Health Management of Pertussis in England</a> or <a href="#">PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings</a> who have not received a dose of pertussis-containing vaccine in the last five years and no Td/IPV vaccine in the preceding month.</p> <p>A dTaP/IPV dose is recommended at any stage of pregnancy for pertussis contacts (in Group 2 b), c) or d))<sup>4</sup>, at increased risk of transmitting to ‘vulnerable’ individuals (in Group 1)<sup>5</sup>, who have not received a pertussis containing vaccine more than 1 week and less than 5 years ago, and who happen to be pregnant as well. Where such vaccination of pregnant contacts occurs before 16 weeks of pregnancy, a further dose of pertussis containing vaccine will be required after 16 weeks of pregnancy in accordance with the routine immunisation schedule and at least 4 weeks after the preceding dose.</p>
<p><b>Duration of treatment</b></p>	<p>See dose section above</p>
<p><b>Quantity to be supplied / administered</b></p>	<p>Single 0.5ml dose per administration.</p>

<sup>4</sup> b) healthcare workers working with infants and pregnant women c) people whose work involves regular, close or prolonged contact with infants too young to be fully vaccinated d) people who share a household with an infant too young to be fully vaccinated

<sup>5</sup> Individuals at increased risk of severe complications (‘vulnerable’): • unimmunised infants (born after 32 weeks) less than 2 months of age whose mothers did not receive pertussis vaccine after 16 weeks of pregnancy and at least 2 weeks prior to delivery • unimmunised infants (born < 32 weeks) less than 2 months of age regardless of maternal vaccine status • unimmunised and partially immunised infants (less than 3 doses of vaccine) aged 2 months and above regardless of maternal vaccine status

<p><b>Supplies</b></p>	<p>Boostrix-IPV® is the recommended product for the vaccination for pregnant women programme. Repevax® (dTaP/IPV) may be used as an alternative if Boostrix-IPV® (dTaP/IPV) vaccine is not available. Either vaccine is recommended for the immunisation of contacts of pertussis.</p> <p>Centrally purchased vaccines for the national immunisation programme for pregnant women can only be ordered via ImmForm and are provided free of charge.</p> <p>Supplies for the vaccination of contacts of pertussis should be sourced directly from manufacturers/wholesalers. Where vaccine cannot be directly sourced from manufacturers/wholesalers, please contact the national immunisation team for further advice.</p> <p>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>).</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>Upon removal from the cold chain, Boostrix®-IPV is stable for 8 hours at 21°C.</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>
<p><b>Drug interactions</b></p>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended for eligible individuals 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>
<p><b>Identification &amp; management of adverse reactions</b></p>	<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. Injection site haematoma, pruritus, warmth and numbness have also been reported.</p> <p>Common adverse reactions include fever, headache, gastrointestinal disturbances (nausea, diarrhoea, vomiting, abdominal pain), arthralgia, myalgia, malaise, and fatigue/asthenia.</p> <p>Hypersensitivity reactions and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions is available in the SPC, at 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/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme at: <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="#">Pregnant? There are many ways to help protect you and your baby</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/parent/carer of possible side effects and their management.</p> <p>The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>When administration is postponed advise the individual/parent/carer 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>Pertussis vaccination is recommended after the fetal anomaly scan to prevent any identified anomalies being inappropriately attributed to vaccination. The fetal anomaly scan usually takes places between 18<sup>+0</sup> and 20<sup>+6</sup> weeks gestation. Mothers declining the anomaly scan should continue to be offered pertussis vaccination.</p> <p>If a person has received vaccination for a tetanus-prone wound from week 16 of this pregnancy with a vaccine also containing pertussis antigen then the additional dose in pregnancy using Boostrix<sup>®</sup>-IPV or Repevax<sup>®</sup> would not be required, refer to advice in the 'The Green Book' <a href="#">Chapter 30</a>.</p> <p>Women who have never received (or not completed) a primary schedule of vaccination against diphtheria, tetanus and polio should be offered a single dose of dTaP/IPV in accordance with this PGD. They should then be offered Td/IPV (eg Revaxis<sup>®</sup>) at appropriate intervals if any subsequent doses of vaccine are needed to complete a three dose primary course. See <a href="#">PHE Vaccination of individuals with uncertain or incomplete immunisation status</a>.</p>
<b>Records</b>  Continued over page	<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> </ul>

<p><b>Records</b> continued</p>	<ul style="list-style-type: none"> <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 password controlled immunisers 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 and the electronic and/or hand-held maternity record (if available). 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 Services team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement.</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>
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## 6. Key references

<p>Key references</p> <p>Continued over page</p>	<p><b>dTaP/IPV vaccine</b></p> <ul style="list-style-type: none"><li>• Immunisation Against Infectious Disease: The Green Book <a href="#">Chapter 15</a> and <a href="#">Chapter 26</a>. Updated 19 April 2013. <a href="#">Chapter 30</a>. Updated 26 November 2018. <a href="#">Chapter 24</a>. Updated 07 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 Boostrix<sup>®</sup>-IPV, GlaxoSmithKline. 19 January 2018. <a href="http://www.medicines.org.uk/emc/medicine/28679">http://www.medicines.org.uk/emc/medicine/28679</a></li><li>• Summary of Product Characteristic for Repevax<sup>®</sup>, Sanofi Pasteur. 9 January 2018. <a href="http://www.medicines.org.uk/emc/medicine/15256">http://www.medicines.org.uk/emc/medicine/15256</a></li><li>• Vaccination against pertussis (whooping cough) for pregnant women: information for healthcare professionals. 22 June 2016. <a href="https://www.gov.uk/government/publications/vaccination-against-pertussis-whooping-cough-for-pregnant-women">https://www.gov.uk/government/publications/vaccination-against-pertussis-whooping-cough-for-pregnant-women</a></li><li>• NHS public health functions agreement 2018-19 Service specification no.1A: Pertussis pregnant women 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 13 November 2017. <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>• 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 Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings. Updated 2 November 2016. <a href="https://www.gov.uk/government/publications/pertussis-guidelines-for-public-health-management-in-a-healthcare-setting">https://www.gov.uk/government/publications/pertussis-guidelines-for-public-health-management-in-a-healthcare-setting</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. <a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li></ul>
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<b>Key references</b> continued	<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><li>• Protocol for ordering storage and handling of vaccines. April 2014. <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></ul>
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## 7. Practitioner authorisation sheet

**Pertussis PGD v04.00 Valid from: 01/04/2019 Expiry: 31/03/2021**

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 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

### 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 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.