UK Health Security Agency

**UKHSA publications gateway number: GOV-14321**

# Pertussis Vaccine Patient Group Direction (PGD)

This PGD is for the administration of low dose diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV) to pregnant women from week 16 of pregnancy, in accordance with the national immunisation programme and to pertussis contacts aged 10 years and over in accordance with Guidelines for the Public Health Management of Pertussis in England and Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings.

This PGD is for the administration of dTaP/IPV vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

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| Reference no: | Pertussis PGD |
| Version no: | 06.00 |
| Valid from: | 31 March 2023 |
| Review date: | 1 October 2024 |
| Expiry date: | 31 March 2025 |

**The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England 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)[1]. **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 UKHSA PGD templates for authorisation can be found from:
https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

[1] This includes any relevant amendments to legislation

Any concerns regarding the content of this PGD should be addressed to: immunisation@ukhsa.gov.uk

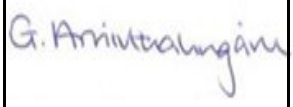
Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.londonimms@nhs.net

## 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 | PHE Pertussis PGD amended to:<br>• reflect service specification for vaccine eligibility 'from 16 weeks of pregnancy' rather than 'from 20 weeks of pregnancy'<br>• reference the protocol for ordering, storage and handling of vaccines<br>• update wording regarding authorisation in line with agreed PHE PGD template changes and multiple practitioner authorisation sheet,<br>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates | 24 March 2017 |
| V04.00 | PHE Pertussis PGD amended to:<br>• 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<br>• include immunisation of contacts of pertussis in accordance with PHE guidelines<br>• remove the off-label status for use in pregnancy<br>• include additional stability statement for Boostrix-IPV® in the storage section<br>• refer to Vaccine Incident Guidelines in off-label and storage sections<br>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates | 11 January 2019 |
| V05.00 | PHE Pertussis PGD amended to:<br>• amend to off-label section to reflect mention of subcutaneous administration in product literature<br>• clarify wording for dose and frequency of administration for contacts<br>• simplify supplies section<br>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates | 18 February 2021 |
| V06.00 | UKHSA Pertussis PGD amended to:<br>• replace 'Public Health England' and 'PHE' with 'UKHSA', including branding and updated contact details.<br>• replace NHS England and NHS Improvement (NHSE/I) with NHS England (NHSE) following completion of merger on 1 July 2022<br>• include a reminder of the need for resuscitation facilities in the event of anaphylaxis<br>• clarify management of pregnant women who have been vaccinated with a pertussis-antigen before and after week 16 of pregnancy, or who have already been infected with whooping cough<br>• clarify management for individuals with a prior history of encephalopathy and encephalitis within 7 days of vaccination | 3 March 2023 |

## 1. PGD development

This PGD has been developed by the following health professionals on behalf of UKHSA:

| Developed by: | Name | Signature | Date |
|---|---|---|---|
| **Pharmacist** (Lead Author) | Christina Wilson<br>Lead Pharmacist – Immunisation and Vaccine Preventable Diseases Division, UKHSA |  | 24 February 2023 |
| **Doctor** | Dr Gayatri Amirthalingam<br>Consultant Epidemiologist - Immunisation and Vaccine Preventable Diseases Division, UKHSA |  | 24 February 2023 |
| **Registered Nurse** (Chair of Expert Panel) | David Green<br>Nurse Consultant – Immunisation and Vaccine Preventable Diseases Division, UKHSA |  | 24 February 2023 |

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group.

### Expert Panel

| Name | Designation |
|---|---|
| Nicholas Aigbogun | Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA |
| Sarah Dermont | Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHS England (NHSE) |
| Ed Gardner | Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead, Southbourne Surgery |
| Michelle Jones | Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board |
| Shamez Ladhani | Paediatric Infectious Disease Consultant, UKHSA |
| Jacqueline Lamberty | Lead Pharmacist Medicines Governance, UKHSA |
| Elizabeth Luckett | Senior Screening and Immunisation Manager, NHSE South West |
| Vanessa MacGregor | Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA |
| Alison Mackenzie | Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSE South West |
| Gill Marsh | Principal Screening and Immunisation Manager/ Nurse Consultant NHS England North West |
| Lesley McFarlane | Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA |
| Mary Ramsay CBE | Director of Public Health Programmes, UKHSA |
| Tushar Shah | Lead Pharmacy Advisor, NHSE London |

## 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 – London authorises this PGD for use by the services or providers listed below:

| Authorised for use by the following organisations and/or services |
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| This PGD must only be used by specified registered healthcare professionals working for providers that are directly commissioned by NHS England - London, or who are administering vaccinations as part of a national immunisation programme, and who have been named and authorised to practice under it. |
| **Limitations to authorisation** |
| None |

| **Organisational approval (legal requirement)** | | | |
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| **Role** | **Name** | **Sign** | **Date** |
| Chief Nurse, NHS England - London | Jane Clegg |  | 24/03/2023 |

| **Additional signatories according to locally agreed policy** | | | |
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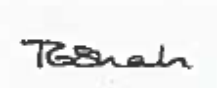
| **Role** | **Name** | **Sign** | **Date** |
| Director of Nursing Leadership and Quality, NHS England – London | Gwen Kennedy |  | 06/03/2023 |
| Lead Pharmacy Advisor, NHS England - London | Tushar Shah |  | 05/03/2023 |

Local enquiries regarding the use of this PGD may be directed to england.londonimms@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

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| **Qualifications and professional registration** | Registered professional with one of the following bodies:<br>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)<br>• pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)<br>• paramedics, physiotherapists and radiographers currently registered with the Health and Care Professions Council (HCPC)<br><br>The practitioners above must also fulfil the Additional requirements detailed below.<br><br>Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD. |
| **Additional requirements** | Additionally, practitioners:<br>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it<br>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines<br>• must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs)<br>• must be familiar with the vaccine products and alert to changes in their Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes<br>• must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training<br>• must be competent to undertake immunisation and to discuss issues related to immunisation<br>• must be competent in the handling and storage of vaccines, and management of the 'cold chain'<br>• must be competent in the recognition and management of anaphylaxis<br>• must have access to the PGD and associated online resources<br>• should fulfil any additional requirements defined by local policy<br><br>**The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.** |
| **Continued training requirements** | 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).<br><br>Practitioners should be constantly alert to any subsequent recommendations from UKHSA, NHSE and other sources of medicines information.<br>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. |

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

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| **Clinical condition or situation to which this PGD applies** | Indicated for the immunisation of women from 16 weeks[2] of pregnancy in accordance with the recommendations given in Chapter 24 of Immunisation Against Infectious Disease: 'The Green Book' and for the immunisation of contacts of pertussis, from 10 years of age, in accordance with Guidelines for the Public Health Management of Pertussis in England or Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings |
| **Criteria for inclusion** | • Pregnant women from 16 weeks of pregnancy.<br>• Mothers with an infant less than 2 months of age who did not receive pertussis vaccination during their pregnancy.<br>• Contacts of pertussis, from 10 years of age for whom pertussis vaccination is recommended in accordance with Guidelines for the Public Health Management of Pertussis in England or Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings |
| **Criteria for exclusion[3]** | Individuals for whom no valid consent has been received.<br>Individuals who:<br>• are less than 16 weeks pregnant (unless identified as a contact at risk of transmitting pertussis to vulnerable individuals)<br>• have been given a dose of diphtheria, tetanus, polio and pertussis (DTaP/IPV)/(dTaP/IPV) or diphtheria, tetanus and poliomyelitis (Td/IPV)-containing vaccine in the last 4 weeks<br>• 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<br>• 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)<br>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)<br>• are defined as a contact of pertussis, aged under 10 years and are unimmunised or partially immunised. Refer to the dTaP/IPV PGD and DTaP/IPV/Hib/HepB PGD as required to bring vaccination up to date.<br>• have an unstable neurological condition, including uncontrolled epilepsy, without an identifiable cause.<br>• have previously developed encephalopathy or encephalitis within 7 days of immunisation with a vaccine containing diphtheria, tetanus, polio or pertussis antigen, without an identifiable cause and resolution of symptoms took longer than 7 days. |
| **Cautions including any relevant action to be taken**<br><br>(continued over page) | Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK).<br>Women who are less than 16 weeks pregnant, requiring protection without delay, such as following a tetanus-prone wound, or in the management of diphtheria or poliomyelitis, should be given Td/IPV instead. Ensure a |

[2] From 16 weeks of pregnancy means a gestation of 16 weeks plus 0 days ($16^{+0}$) or more.

[3] 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

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| **Cautions including any relevant action to be taken**<br><br>(continued) | minimum 4 week gap is observed prior to offering their pertussis vaccine, from week 16 of pregnancy.<br><br>In cases of inadvertent administration of Revaxis®, a dose of dTaP/IPV should be given as soon as the error is realised, and local procedures for medicines error reporting should be followed. More information can be found in Pertussis (whooping cough) vaccination programme for pregnant women: information for healthcare practitioners.<br><br>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with the national recommendations.<br><br>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.<br><br>Individuals with a prior history of developing encephalopathy or encephalitis within seven days of vaccination with a vaccine containing diphtheria, polio or pertussis antigen, may be immunised as normal under this PGD if the cause was identified, or if a complete recovery was made within 7 days. Refer to the Green Book Chapter 24 for further advice. |
| **Action to be taken if the patient is excluded** | If less than 16 weeks pregnant, delay vaccination until indicated, unless post-exposure vaccination is required (as outlined elsewhere in this PGD).<br><br>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.<br><br>Individuals with an unstable neurological condition with no underlying cause should have immunisation deferred until the condition is stable. If the cause is identified, immunisation may proceed. In both instances, a PSD must be used.<br><br>Individuals who previously developed encephalitis or encephalopathy within 7 days of vaccination with dTaP/IPV, Td/IPV or DTaP/IPV, without an identifiable cause and where resolution of symptoms took longer than 7 days, should have immunisation deferred until the condition is stabilised. A PSD must be used.<br><br>Seek appropriate advice from the local Screening and Immunisation Team, the local Health Protection Team or the individual's clinician where appropriate.<br><br>The risk to the individual of not being immunised must be taken into account.<br><br>Document the reason for exclusion and any action taken in the individual's clinical records.<br><br>Inform or refer to the GP or a prescriber as appropriate. |
| **Action to be taken if the patient or carer declines treatment** | Informed consent, from the individual, or a person legally able to act on the individual's behalf, must be obtained for each administration.<br><br>Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications.<br><br>Document advice given and the decision reached.<br><br>Inform or refer to the GP or a prescriber as appropriate. |

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| **Arrangements for referral for medical advice** | As per local policy |

## 5. Description of treatment

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| **Name, strength and formulation of drug** | Low dose diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed):<br>•Boostrix-IPV®, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV<br>• Repevax®, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV |
| **Legal category** | Prescription only medicine (POM) |
| **Black triangle▼** | No |
| **Off-label use** | Vaccines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to Vaccine Incident Guidance. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.<br>Where a vaccine is recommended off-label, consider, as part of the consent process, informing the individual, parent or carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. |
| **Route and method of administration** | Administer by intramuscular injection, preferably into the deltoid region of the upper arm.<br>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.<br>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' Chapter 4).<br>Both Boostrix-IPV® and Repevax® appear as uniform, cloudy white suspensions which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine.<br>The vaccine should not be used if discoloured or foreign particles are present in the suspension.<br>The vaccine SPCs provides further guidance on administration and are available from the electronic Medicines Compendium website |
| **Dose and frequency of administration**<br><br>(continued over page) | Single 0.5ml dose per administration<br>**Routine immunisation in pregnancy schedule**<br>A single dose of dTaP/IPV should 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. |

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| **Dose and frequency of administration**<br><br>(continued) | 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.<br><br>Vaccination is indicated in each pregnancy.<br><br>For women who have not received the vaccine in pregnancy, pertussis-containing vaccine can be offered to mothers in the 2 months following birth, up until their child receives their first dose of pertussis-containing vaccine. This is to reduce the risk of the mother contracting pertussis in the post-partum period and passing it on to her infant.<br><br>If a pregnant woman receives a dose of pertussis-containing vaccine after week 16 of pregnancy for occupational or contact purposes, this dose is considered valid for the maternity vaccine schedule, and no further doses are required in that pregnancy.<br><br>**Public health management of pertussis**<br><br>A single dose of dTaP/IPV should be administered to contacts recommended immunisation in accordance with Guidelines for the Public Health Management of Pertussis in England or Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings who have not received a dose of pertussis-containing vaccine in the last 5 years and no Td/IPV vaccine in the preceding 4 weeks.<br><br>As outlined in the above Guideline, a single dTaP/IPV dose is recommended at any stage of pregnancy for pertussis contacts (in Groups 2 b, 2c or 2d)[4], at increased risk of transmitting to vulnerable individuals (in Group 1)[5], who have not received a pertussis-containing vaccine in the last 5 years, 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. |
| **Duration of treatment** | See **Dose and frequency of administration** above |
| **Quantity to be supplied and administered** | Single 0.5ml dose per administration. |
| **Supplies**<br><br>(continued over page) | Centrally purchased vaccines for the national immunisation programme for pregnant women can only be ordered via ImmForm and are provided free of charge.<br><br>Though Boostrix-IPV® is utilised primarily for this cohort, if not available, Repevax® may be given on a like-for-like basis.<br><br>Infanrix-hexa® or Infanrix-IPV+Hib® should not be given in the maternity programme as the higher antigenic content increases the likelihood of localised adverse reactions. |

[4] **Group 2b**:healthcare workers working with infants and pregnant women **Group 2c:** people whose work involves regular, close or prolonged contact with infants too young to be fully vaccinated **Group 2d:** people who share a household with an infant too young to be fully vaccinated

[5] **Group 1 -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

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| **Supplies**<br>(continued) | Supplies for the vaccination of contacts of pertussis should be sourced directly from manufacturers or their wholesalers. Where vaccine cannot be directly sourced from manufacturers or wholesalers, please contact the national immunisation team for further advice.<br>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3). |
| **Storage** | Store at +2°C to +8°C.<br>Store in original packaging to protect from light.<br>Do not freeze.<br>Upon removal from the cold chain, Boostrix-IPV® is stable for 8 hours at 21°C.<br>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 Vaccine Incident Guidance. |
| **Disposal** | 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 arrangements and NHSE guidance (HTM 07-01): Management and disposal of healthcare waste |
| **Drug interactions** | Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended for eligible individuals even if the antibody response may be limited.<br>Boostrix-IPV® and Repevax® may be given at the same time as other vaccines.<br>A detailed list of drug interactions is available in the SPCs, which are available from the electronic Medicines Compendium. |
| **Identification and management of adverse reactions** | The following adverse reactions are common to both Boostrix-IPV® and Repevax®.<br>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. Injection-site haematoma, pruritus, warmth and numbness have also been reported.<br>Common adverse reactions include fever, headache, gastrointestinal disturbances (nausea, diarrhoea, vomiting, abdominal pain), arthralgia, myalgia, malaise, and fatigue/asthenia.<br>Hypersensitivity reactions and anaphylaxis can occur but are very rare.<br>A detailed list of adverse reactions is available in the SPC, at the electronic Medicines Compendium. |
| **Reporting procedure of adverse reactions** | Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store.<br>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. |

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| **Written information to be given to patient or carer** | Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate:<br>• Pregnancy: how to help protect you and your baby<br>• Whooping cough: vaccination in pregnancy programme resources<br>For resources in accessible formats and alternative languages, please visit https://www.healthpublications.gov.uk/. |
| **Patient advice and follow up treatment** | As the pertussis vaccines also contain antigens against diphtheria, tetanus and polio, vaccination against pertussis offers additional protection against these other diseases.<br>Inform the individual, parent or carer of possible side effects and their management<br>The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card scheme.<br>When administration is postponed advise the individual, parent or carer when to return for vaccination. |
| **Special considerations and additional information** | Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.<br>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 $18^{+0}$ and $20^{+6}$ weeks gestation. Mothers declining the anomaly scan should continue to be offered pertussis vaccination.<br>If a pregnant woman received pertussis-containing vaccine before week 16 of her pregnancy, either in error or for occupational or contact reasons, then she should be offered a second dose when she reaches 16 weeks of pregnancy, or around the time of her antenatal fetal anomaly scan. The dose should be repeated to maximise the antibodies that are transferred across the placenta to her unborn baby. If a repeat dose is required, there should be an interval of at least 4 weeks from the previous dose to minimise the risk of local reaction.<br>If a pregnant woman has received a dose of pertussis-containing vaccine after week 16 of pregnancy for occupational or contact reasons, this should be counted as a valid dose and she would not need a repeat dose during that pregnancy.<br>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 (Revaxis®) at appropriate intervals if any subsequent doses of vaccine are needed to complete a 3 dose primary course. See Guidance - Vaccination of individuals with uncertain or incomplete immunisation status.<br>If a woman has had confirmed or suspected whooping cough during pregnancy, she should still be offered the pertussis vaccine. Not all women produce sufficiently high levels of antibodies after an infection, to pass on across the placenta to the infant. |

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| **Records** | Record:<br>• that valid informed consent was given.<br>• name of individual, address, date of birth and GP with whom the individual is registered<br>• name of immuniser<br>• name and brand of vaccine<br>• date of administration<br>• dose, form and route of administration of vaccine<br>• quantity administered<br>• batch number and expiry date<br>• anatomical site of vaccination<br>• advice given, including advice given if excluded or declines immunisation<br>• details of any adverse drug reactions and actions taken<br>• supplied via PGD<br><br>Records should be signed and dated (or a password-controlled immuniser's record on e-records).<br><br>All records should be clear, legible and contemporaneous.<br><br>This information should be recorded in the individual's GP record and both the electronic and hand-held maternity records (if available). Where vaccine is administered outside the GP setting, appropriate health records should be kept and the individual's GP informed.<br><br>The local Child Health Information Services team (Child Health Records Department) must be notified using the appropriate documentation or pathway as required by any local or contractual arrangement.<br><br>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. |

## 6. Key references

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| **Key references** | **dTaP/IPV vaccine**<br>• Immunisation Against Infectious Disease: The Green Book. Chapter 15 and Chapter 26, last updated 19 April 2013. Chapter 30, last updated 6 June 2022. Chapter 24, last updated 7th April 2016. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book<br>• Summary of Product Characteristic for Boostrix-IPV®, GlaxoSmithKline. Updated 8 September 2022. http://www.medicines.org.uk/emc/medicine/28679<br>• Summary of Product Characteristic for Repevax®, Sanofi Pasteur. Updated 13 August 2021. http://www.medicines.org.uk/emc/medicine/15256<br>• Vaccination against pertussis (whooping cough) for pregnant women: information for healthcare practitioners, UKHSA, last updated 6 September 2021. https://www.gov.uk/government/publications/vaccination-against-pertussis-whooping-cough-for-pregnant-women<br>• Vaccination of individuals with uncertain or incomplete immunisation status, UKHSA. Updated 17 March 2022. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status<br>• Guidelines for the Public Health Management of Pertussis in England. Published May 2018. https://www.gov.uk/government/publications/pertussis-guidelines-for-public-health-management<br>• Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings. Updated 2 November 2016. https://www.gov.uk/government/publications/pertussis-guidelines-for-public-health-management-in-a-healthcare-setting<br><br>**General**<br>• NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health. 20 March 2013. https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/<br>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners<br>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2<br>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources<br>• UKHSA Immunisation Collection. https://www.gov.uk/government/collections/immunisation<br>• Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration. Updated July 2022. https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors |

**Practitioner authorisation sheet**

**Pertussis PGD v06.00 Valid from: 31 March 2023 Expiry: 31 March 2025**

Before signing this patient group direction (PGD), check that the document has had the necessary authorisations in section 2. 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 |
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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 the following named organisation …… 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.