UK Health Security Agency

Publications gateway number: GOV-15609

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 in England, 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:	v5.00
Valid from:	1 November 2023
Review date:	1 May 2025
Expiry date:	1 November 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 Immunisation PGD templates for authorisation can be found from: Immunisation patient group direction (PGD) templates

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

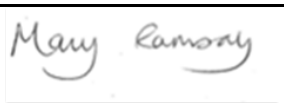
[1] This includes any relevant amendments to legislation

Change history

Version	Change details	Date
V1.00	New PHE PGD template	15 December 2015
V2.00	DTaP/IPV PGD routine review and amended to: • include vaccination in line with recommendations for the management of diphtheria or polio • remove exclusions regarding timing of previous vaccination (see dose section for schedules) • remove exclusions relating to neurological conditions and encephalopathy and relevant advice moved to the cautions section • update off-label section in relation to amended exclusions • update dose section with management of cases and contacts of polio and diphtheria • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	29 September 2017
V3.00	dTaP/IPV PGD routine review and amended to: • removed the DTaP/IPV (Infanrix®-IPV) product as not currently marketed in the UK • include Boostrix®-IPV • include individuals identified by an Outbreak Control Team for immunisation in response to a school/nursery pertussis outbreak • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	22 October 2019
V4.00	dTaP/IPV PGD routine review and amended to: • update off-label section • rebrand from PHE to UKHSA and include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	20 October 2021
V5.00	dTaP/IPV PGD routine review and amended to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change, gateway requirements and other UKHSA PGDs • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 • add facilities for management of anaphylaxis in cautions section • add syncope (vasovagal reaction) in cautions section as per SPCs • add individuals with HIV infections in cautions section add statement for regarding absence of reliable history for routine immunisation in dose and frequency section • amend criteria for inclusion and doses and frequency sections stating pertussis outbreak in nurseries/schools to contacts and cases as per the guidelines • clarify the section for management of tetanus prone wounds • add the updated storage conditions as per SPCs • add signposting to accessible information in written information provided • update references	24 October 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)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		25 October 2023
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		25 October 2023
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		25 October 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

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingham	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Alison Campbell	Screening and Immunisation Coordinator,Public Health Commissioning NHS England (NHSE) Midlands
Rosie Furner	Pharmacist - Medicines Governance, Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nicola Philbin	Screening and Immunisation Manager, Vaccination and screening programmes – Public Health Commissioning NHSE Midlands
Laura Smeaton	IDPS Programme Projects Manager and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme, NHS England (NHSE)
Tushar Shah	Lead Pharmacy Adviser, NHSE London

2. Organisational authorisations

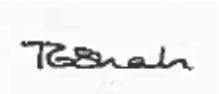
The PGD is not legally valid until it has had the relevant organisational authorisation.

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
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)			
Role	**Name**	**Sign**	**Date**
Chief Nurse, NHS England - London	Jane Clegg		31/10/2023

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Director of Nursing Leadership and Quality, NHS England – London	Gwen Kennedy		30/10/2023
Lead Pharmacy Adviser, NHS England – London	Tushar Shah		30/10/2023

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

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

Clinical condition or situation to which this PGD applies	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 Chapter 15, Chapter 24, Chapter 26 and Chapter 30 of Immunisation Against Infectious Disease: the 'Green Book' and associated disease management guidelines (see Dose and frequency of administration section)
Criteria for inclusion	Individuals from 3 years 4 months to under 10 years of age who: • 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) Individuals from 3 years of age (see Additional information regarding individuals over 10 years) who: • have a tetanus-prone wound and tetanus immunisation is recommended in accordance with Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds or tetanus boosters are due soon and it is convenient to give now (see the 'Green Book' Chapter 30) • require vaccination in line with the national recommendations for the management of cases and contacts of diphtheria or polio (see dose and frequency) • are identified by an Outbreak Control Team for immunisation in the management of cases and contacts in a pertussis outbreak, in accordance with the Guidelines for the Public Health Management of Pertussis in England.
Criteria for exclusion[2]	Individuals for whom valid consent or best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent, see Chapter 2 of the Green Book). Several resources are available to inform consent (see written information to be given to individual or carer section). Individuals who: • 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 • 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) • have not yet completed primary immunisation with three doses of diphtheria, tetanus, pertussis and poliomyelitis antigen unless recommended by an Outbreak Control Team • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken 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. If a seizure associated with a fever occurred within 72 hours of a previous immunisation with pertussis containing vaccine,

[2] 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

Cautions including any relevant action to be taken (continued)	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. 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. 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. The immunogenicity of the vaccine could be reduced in individuals with immunosuppression or HIV infection (regardless of CD4 count). Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek specialist advice as appropriate. Individuals with immunosuppression or HIV infection 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' Chapter 30 and Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds). Syncope (vasovagal reaction), or fainting, can occur during any vaccination, most commonly amongst adolescents and adults. Some individuals may also experience panic attacks before vaccination. Fainting and panic attacks occurring before or very shortly after vaccination are not usually direct side effects (adverse reactions) of the vaccine but events associated with the injection process itself.
Action to be taken if the patient is excluded Continued over page	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. 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. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team, Outbreak Control Team or the individual's clinician where appropriate. The risk to the individual of not being immunised must be taken

Action to be taken if the patient is excluded (continued)	into account. Document the reason for exclusion and any action taken in the individual's clinical records. 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 person's behalf, must be obtained for each administration. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of 'The Green Book'. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document the advice given, and the decision reached. Inform or refer to the GP as appropriate.
Arrangements for referral	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed): • Repevax®, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV • Boostrix®-IPV, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	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 Chapter 24 of Immunisation Against Infectious Disease: the 'Green Book'. 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 national guidelines (see Dose and frequency of administration). Vaccine 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 vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. 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.
Route and method of administration	Administer by intramuscular injection, preferably into deltoid region of the upper arm. 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. 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' Chapter 4 or the product's SPC. 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. The vaccine should not be used if discoloured or foreign particles are present in the suspension.

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Route and method of administration (continued)	The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website.
Dose and frequency of administration	Single 0.5ml dose per administration **Routine childhood immunisation schedule** 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. 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. **Individuals with unknown or incomplete immunisation status** Children coming from developing countries, from areas of conflict, or from hard-to-reach population groups may not have been fully immunised. Where there is no reliable history of previous immunisation, it should be assumed that they are unimmunised and the full UK recommendations should be followed (see Chapter 11 on vaccine schedules). Where children coming to the UK from some countries may 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. **Management of tetanus prone wounds** Individuals with tetanus-prone wounds should be risk assessed and vaccinated in accordance with the recommendations in the 'Green Book' Chapter 30 Table 30.1 and Guidance on the management of suspected tetanus cases and the assessment and management of tetanus-prone wounds. Individuals with incomplete or uncertain history of immunisation should be offered vaccination to complete the recommended schedule (see Chapters 30 and 11) to protect against future exposures. In accordance with those recommendations, individuals who are severely immunosuppressed may require additional boosting. Individuals may also require human tetanus immunoglobulin (see national guidelines and Chapter 30). Administration of tetanus immunoglobulin is not covered by this PGD. **Management of cases and contacts of diphtheria** Cases and contacts of diphtheria should be managed in accordance with Public health control and management of diphtheria (in England and Wales) guidelines and recommendations from the local health protection team. Individuals who are fully immunised but have not received diphtheria containing vaccine in last 12 months may be given a single booster dose of diphtheria containing vaccine. **Management of cases and contacts of a pertussis outbreak** Cases and contacts of pertussis outbreak should be managed in

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Dose and frequency of administration (continued)	accordance with Guidelines for the Public Health Management of Pertussis in England and recommendations from the Outbreak Control Team**.** **Management of cases and contacts of polio** Cases and contacts of polio should be managed in accordance with National polio guidelines: Local and regional services guidelines and recommendations from the local health protection team. 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.
Duration of treatment	A single booster dose. 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.
Quantity to be supplied and administered	Single 0.5ml dose per administration.
Supplies	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. Vaccine for indications other than the national immunisation programme should be obtained from manufacturers/wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. Discard the vaccine if it has frozen. Further storage information Repevax®: stability data indicate that the vaccine components are stable at temperatures up to 25°C for 72 hours. At the end of this period, the vaccine should be used or discarded. Boostrix®IPV: upon removal from the refrigerator, the vaccine is stable for 8 hours at 21°C. Discard the vaccine if it was not used during this period. See individual SPCs for further storage information. 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 guidance in the technical memorandum 07-01: Safe management of healthcare waste (NHSE,2022).

Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment or with HIV infection. Vaccination is recommended even if the antibody response may be limited. The vaccine may be given at the same time as other vaccines. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website.
Identification and management of adverse reactions	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. Common adverse reactions include fever, irritability, headache, nausea, diarrhoea, vomiting, rash, arthralgia, appetite loss, malaise, fatigue/asthenia, dermatitis, bruising and pruritus. Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium website.
Reporting procedure of adverse reactions	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 or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. If applicable, inform the individual/parent/carer that PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium). Immunisation promotional material may be provided as appropriate, such as Pre-school immunisations: guide to vaccinations (2 to 5 years)
Patient advice and follow up treatment	Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations and additional information Continued over page	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Individuals should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes. The dTaP/IPV (Repevax® or Boostrix®-IPV) vaccine contains a lower dose of pertussis antigen, as well as a lower dose of diphtheria antigen, compared to DTaP/IPV (Infanrix®-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

Special considerations and additional information (continued)	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 Vaccination of individuals with uncertain or incomplete immunisation status 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. 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. Pertussis vaccination may be recommended for individuals over 10 years of age under inclusion criteria which is not covered by this PGD (see Pertussis PGD).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' Chapter 30). 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.
Records Continued over page	Record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of vaccinator • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines vaccination • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password-controlled vaccinator's record on e-records). All records should be clear, legible and contemporaneous. 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. The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate

Records (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.

6. Key references

Key references	**The dTaP/IPV vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 15, Chapter 26 updated 19 April 2013, Chapter 30 updated 6 June 2022 and Chapter 24 updated 7 April 2016 www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Repevax®, Sanofi Pasteur. 8 February 2023. www.medicines.org.uk/emc/medicine/15256 • Summary of Product Characteristic for Boostrix®-~IPV, GlaxoSmithKline UK. 20 July 2023. www.medicines.org.uk/emc/product/5302 • Vaccination of individuals with uncertain or incomplete immunisation status. 17 August 2023. www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status • Public health control and management of diphtheria (in England and Wales) guidelines. Published 16 August 2023. www.gov.uk/government/publications/diphtheria-public-health-control-and-management-in-england-and-wales • Guidelines for the Public Health Management of Pertussis in England. Published May 2018. www.gov.uk/government/publications/pertussis-guidelines-for-public-health-management • National polio guidelines: Local and regional services. UKHSA 26 September 2019. www.gov.uk/government/publications/polio-national-guidelines • Guidance on the management of suspected tetanus cases and the assessment and management of tetanus-prone wounds. 18 September 2023 www.gov.uk/government/publications/tetanus-advice-for-health-professionals/guidance-on-the-management-of-suspected-tetanus-cases-and-the-assessment-and-management-of-tetanus-prone-wounds **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHSE, 2022. NHS England » (HTM 07-01) Management and disposal of healthcare waste • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

dTaP/IPV PGD v5.00 Valid from: 1 November 2023 Expiry: 1 November 2025

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 the following named organisation …… 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.