Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

Diphtheria, Tetanus, Acellular Pertussis and Inactivated Poliomyelitis Vaccine (dTaP/IPV)

by registered Healthcare Professionals

to

individuals from 3 years 4 months to under 10 years of age, in accordance with the national immunisation programme,

or

for the management of cases and contacts of diphtheria, tetanus, pertussis or poliomyelitis from 3 years of age

in Powys Teaching Health Board

Version number: PGD 0073-F

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Reference Number: PGD0073-F
Valid from: 01/11/2025
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Change History

Version number	Change details	Date
PGD0073	Initial issue of PGD (PGD replaced PSD008-A)	01/06/2014
PGD0073-A	Review issue	01/04/2017
PGD0073-B	Review issue DTaP/IPV PGD routine review and amended to: • include management of tetanus prone wounds in the age group • 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 tetanus prone wounds include minor rewording, layout and formatting changes clarity and consistency with other PTHB PGD templates	30/10/2019
PGD0073-C	Review issue and use of PHE template	22/03/2021
PGD0073-D	Review and PHE adoption to include: • 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	02/11/2021
PGD 0073-E	Review issue using UKHSA template v5.00- 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 and PTHB 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	15/11/2023

	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	
PGD 0073-F	Review issue using UKHSA template v6.00- amended to: • update name, strength and formulation section to reflect the pre-school booster vaccine switch from Boostrix-IPV® to Repevax® • Page 1; updated governance requirements for sections 2 and 7 • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • update qualifications and professional registration with reference to clinical scope • add pharmacy technicians in Section 3, qualifications and professional registration • update qualifications and professional registration section to include dieticians, podiatrists, and occupational therapists • update expert panel • update the PGD as per updated UKHSA PGD template 2025 • update cautions section to reflect the changes in the relevant update Green Book Chapters, 2025 for systemic and local reactions • remove statement for encephalopathy and encephalitis and updated the section to provide the guidance for the presence, or a history, of a	01/11/2025

	neurological condition as per updated Chapter 24, 2025 • add off-label use of Boostrix® in relation to transient thrombocytopenia • add guidance statement in relation to missed hexavalent vaccine at 18 months of age, in dose and frequency section • remove statement with reference individuals who have received diphtheria, tetanus and polio vaccine at 18 months overseas • add statement with regard to administering the booster at 3 years 4 months regardless of the overseas vaccination history • add guidance for individuals with unknown or incomplete immunisation status who have had bivalent OPV or fIPV vaccine overseas • clarify duration of treatment section • update references	

This Powys Teaching Health Board PGD is based on a template developed by the following health professionals on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy (also ratified by the UKHSA Medicines Governance Group).

Developed by the following health professionals on behalf of the UKHSA:

Developed By:	Name
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Expert Panel

Name	Designation
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Alison Campbell	Screening and Immunisation Coordinator, Public Health Commissioning NHS England (NHS England) Midlands
Jodie Crossman	Clinical Nurse Specialist GUM – Brighton SHAC, Co-Chair – STI Foundation
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Rosie Furner	Advanced Specialist Pharmacist- Medicines Governance, Specialist Pharmacy Services (SPS)
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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Nilufa Hossain**	Assistant Medical Director for PTHB	Signed by: Nilufa Hossain C21D3F727B964FB...	10/29/2025
Chief Pharmacist **Jonathan Boyd**	Chief Pharmacist for PTHB	Signed by: Jon Boyd 6D8ECFE8C9EB423...	10/29/2025
Senior representative of professional group using the PGD **Paul Hooton**	Executive Director of Nursing and Midwifery for PTHB	Signed by: Paul Hooton EEABC83AC83F4B9...	10/28/2025
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	10/29/2025

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Those using this PGD must ensure that it is organisationally authorised and signed 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.**

The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

[1] This includes any relevant amendments to legislation

PGD adoption by the provider

Name	Job title and organisation	Signature	Date

1. Characteristics of staff

Qualifications and professional registration	• All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the section below: nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) paramedics, physiotherapists, dieticians, podiatrists, and occupational therapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Appendix A – Staff Accredited to use this Patient Group Direction 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 have completed Patient Group Directions training (available via ESR at https://my.esr.nhs.uk or eLearning for Healthcare (e-LfH) at http://www.e-lfh.org.uk/programmes/patient-group-directions/) • 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 and online training. Please contact PTHB immunisation co-ordinator for further information. • Must be competent in intramuscular injection techniques • 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. Completion of cold chain training via https://www.youtube.com/watch?v=m2tDUgV-roE (also available via ESR) • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the recognition, management and reporting of adverse drug reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Life Support skills (Basic Life Support Skills are PTHB standard). • 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). Evidence of ongoing PGD training to be submitted to Line Manager annually. Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. Practitioners must make a self-declaration of competency on PADR. Compliance with all mandatory NHS training. Practitioners should be constantly alert to any subsequent recommendations from UKHSA and/or

	NHSE and/or Welsh Government and/or Public Health Wales and/or NHS Wales 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. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**

2. 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) **It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.**
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 Public Health Wales guidance Informed consent, from a person legally able to act on the individual's behalf, must be obtained prior to administration. Medical and drug history taken, no reason for exclusion **NB** Refer to PTHB Consent to Treatment and Examination Policy
Criteria for exclusion (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)	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) Refer to sections "Action to be taken if the patient is excluded" and "Action to be taken if the patient or carer declines treatment".

Cautions including any relevant action to be taken	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. **Systemic and local reactions following a previous immunisation** **Pertussis containing vaccine** Immunisation with pertussis-containing vaccine should continue following a history of a severe or mild systemic or local reaction within 72 hours of a preceding vaccine. This includes following reactions: • fever, irrespective of its severity • hypotonic-hyporesponsive episodes (HHE) • persistent crying or screaming for more than three hours • severe local reaction, irrespective of extent Individuals who have had severe reactions, as above, have continued and completed immunisation with pertussis-containing vaccines without recurrence of these reactions (for further information see Chapter 24) **Diphtheria and tetanus containing vaccines** Individuals who have had a systemic or local reaction following a previous immunisation with a diphtheria or tetanus containing vaccine can continue to receive subsequent doses of diphtheria and tetanus containing vaccine. This includes the following rare reactions: • fever, irrespective of its severity • hypotonic-hyporesponsive episodes (HHE) • persistent crying or screaming for more than three hours • severe local reaction, irrespective of extent • convulsions, with or without fever, within 3 days of vaccination For further information see Chapter 15 and Chapter 30. Other considerations: The presence, or a history, 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 (see Chapter 24). 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 medical 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. Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847

	Advice can also be sought from local Safeguarding Leads.
Action to be taken if the individual is excluded	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 PGD0141). 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 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 individual 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 and recorded appropriately. The Patient information leaflet (PIL) for the vaccine to be used should be available to inform consent. 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 advice given, and the decision reached. Inform or refer to the GP as appropriate. Inform Child Health if appropriate – if any vaccination is declined for a child under 19 years of age, child health must be informed and the appropriate form completed.
Arrangements for referral for medical advice	Refer to GP, paediatrician or consultant in communicable disease control (CCDC) for clinical advice as necessary. Document any advice given.

3. 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 For full formulation see SPC **Note:** The primary vaccine used for the pre-school booster diphtheria, tetanus, acellular pertussis and polio (dTaP/IPV) vaccination is Repevax®. • Boostrix®-IPV, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV For full formulation see SPC
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 in accordance with the neurological conditions section in Chapter 24 of Immunisation Against Infectious Disease: the 'Green Book'. Boostrix-IPV® SPC states that the vaccine should not be administered to individuals who have experienced

	transient thrombocytopenia or neurological complications, however, it can be given in accordance with the relevant chapters of 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 All Wales Advisory document on Ordering Storage and Handling of Vaccines and 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 (see The Green Book Chapter 4). 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. 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. **Delay in primary course** 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. **Missed primary course vaccinations** Where an individual has completed their primary immunisations before the age of 1 year and presents for their pre-school booster (at three years four months of age or soon thereafter) but missed their hexavalent at 18 months of age, the hexavalent, Hib-containing vaccine (DTaP/IPV/Hib/HepB) should be offered as their first booster dose (see Hexavalent PGD). This is to ensure they receive a Hib booster over 1 year of age. **Individuals with uncertain 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). Doses of DTaP-containing vaccines given additionally to the primary course under 3 years of age (e.g. at 18 months) do not replace the need to give the dose of dTaP/IPV vaccine (first booster) from 3 years 4 months. There should be a minimum one-year interval between the first booster and any previous dose of DTaP-containing vaccine received. **Bivalent OPV (bOPV)** Any dose(s) of OPV received in another country prior to April 2016 would have been trivalent OPV (tOPV) and can be counted as valid. In April 2016 tOPV was withdrawn and replaced with the bivalent OPV (bPOV), which contains only attenuated virus of types 1 and 3. Therefore children vaccinated with OPV from 2016 onwards may not have protection against all the antigens currently used in the UK. Any dose of OPV that has been received in another country since April 2016 should be discounted and the OPV doses received as part of the routine childhood schedule should be replaced by doses of IPV-containing vaccine appropriate for age (see Chapter 26). Most countries have a mixed OPV and IPV schedule and so if sufficient IPV doses have been received for their age, then no additional IPV doses are needed. The routine pre-school and subsequent boosters should be given according to the UK schedule. For further information see Vaccination of individuals with uncertain or incomplete immunisation status algorithm. **Fractional IPV (fIPV)** Fractional IPV is offered in some countries as part of the routine schedule. fIPV is one fifth of the IPV dose. An individual newly arrived in the UK who has received fIPV doses instead of full doses has not therefore had 'sufficient doses' of polio antigen. They should receive

	any outstanding vaccines using the full dose vaccine to catch-up with the UK schedule (see Chapter 26). **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. Individuals who are severely immunosuppressed may not be adequately protected against tetanus, despite having been fully immunised and additional booster doses may be required. 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 accordance with Guidelines for the Public Health Management of Pertussis in England and recommendations from the Outbreak Control Team and/or guidance from Public Health Wales/Welsh Government. **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 – PGD0141) and subsequent boosters (that is the Td/IPV adolescent booster – PGD0182) to complete immunisation in accordance with national recommendations.
Quantity to be 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). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.
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 or protocols for the storage and handling of vaccines (see All Wales Advisory document on Ordering Storage and Handling of Vaccines and Green Book Chapter 3). Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk), and via the Once for Wales Reporting System.
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) and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
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: www.medicines.org.uk

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: www.medicines.org.uk
	
	In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use:
	Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone.
	
	In case of anaphylaxis:-
	• Refer to adrenaline (epinephrine) PGD PGD0017 and anaphylaxis policy
	  • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E
	  • Ensure reaction is fully documented in patient notes
	  • Ensure all patient records are marked **ALLERGIC TO diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV)**
	  • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers
	
	Report via Once for Wales Reporting System.

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 at: http://yellowcard.mhra.gov.uk 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. All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Where 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 vaccinations: guide to vaccinations from 2 to 5 years - GOV.UK or "Diphtheria, Tetanus, Pertussis and Polio vaccine for children before they start school" leaflet. Information for printing and website links suitable for patients can be found on NHS 111 Wales and Public Health Wales Health Information Resources.
Advice and follow up treatment	Give appropriate advice if medication is used off-label. 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	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a working 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 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 (refer to PGD0182). 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 PGD0072). 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	Record consultation details as required by local procedures. The practitioner must ensure the following is recorded: • 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 • administered via PGD, record PGD version number. Records should be signed and dated (or 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 documentation/pathway as required by any local or contractual arrangement. Up to 18 years of age forward a notification of vaccination given to Child Health Department (based in Brecon Hospital for under 5 years and Llandrindod Hospital for school age).

	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references	The dTaP/IPV vaccine

- Immunisation Against Infectious Disease: The Green Book Chapter 26 updated 2 June 2025, Chapter 15, updated 3 June 2025,Chapter 30 updated 3 June 2025 and Chapter 24 updated 10 June 2025 www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Summary of Product Characteristic for Repevax®, Sanofi Pasteur. 4 June 2025 www.medicines.org.uk/emc/medicine/15256
- Summary of Product Characteristic for Boostrix® IPV, GlaxoSmithKline UK. 20 November 2024. www.medicines.org.uk/emc/product/5302
- Vaccination of individuals with uncertain or incomplete immunisation status. 9 July 2025. 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. Updated 17 July 2025. 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. Updated 15 August 2024. 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. 15 March 2024 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

- All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition September 2017
- Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste
- NHS England, 2022 NHS England » (HTM 07-01) Management and disposal of healthcare waste

	• National Minimum Standards and Core Curriculum for Immunisation Training. Published 31 July 2025. 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

Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager may wish to use the competency checklist (below).*

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 Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of health professional	Signature of health professional	Printed name of senior representative authorising health professional (Authorising Manager)	Signature of senior representative authorising health professional (Authorising Manager)	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 25 years after the PGD expires. The healthcare professional should retain a copy of the document after signing

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " comments"	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.