



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. Healthcare 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

low-dose diphtheria, tetanus and inactivated poliomyelitis vaccine (Td/IPV)

to individuals from 10 years of age. This PGD supports delivery of the [school-age booster](#) from Year 9 onwards in accordance with the national immunisation programme. This PGD is also used for the administration of Td/IPV vaccine for the management of tetanus-prone wounds and cases and contacts of either diphtheria or poliomyelitis in an outbreak according to respective national guidelines (this PGD may be used for individuals from 6 years of age for the management of cases and contacts of polio in an outbreak). The PGD may also be used for individuals travelling to high-risk areas.

by registered healthcare professionals

in Powys Teaching Health Board

Version number: PGD 0182 B

Change History

Version number	Change details	Date
PGD 0182	Review issue to replace PGD0023 and PGD0045 to unify with PHE template PGD scope. Td/IPV (Revaxis®) PGD PHE template adoption to include: routine review and amended to: <ul style="list-style-type: none"> • rebrand from PHE to UKHSA • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates 	3/11/2021
PGD0182A	Td/IPV (Revaxis®) PGD reviewed and amended to: <ul style="list-style-type: none"> • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 • add management of cases and contacts in an outbreak of polio in accordance with the national guidelines and recommendations from the local health protection teams • add information for vaccinating individuals with family history of seizures, children coming in to UK where history of immunisation is not known and children with partial and unknown history of immunisation as per Green Book Chapter 26 and SPCs in the special consideration and additional information section • updated safeguarding information 	15/08/2022
PGD0182B	Review issue in line with UKHSA PGD template Td/IPV (Revaxis®) v6.00 to: <ul style="list-style-type: none"> • include minor rewording or additions of standard text, layout and formatting changes for clarity and consistency with other UKHSA PGD templates • remove the advice to defer vaccination in individuals with a history of developing encephalopathy or encephalitis within 7 days of receiving a vaccine containing either pertussis, 	04/08/2024

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	<p>diphtheria, polio or tetanus and where resolution of symptoms took longer than 7 days, in line with Chapter 30 of the Green Book</p> <ul style="list-style-type: none"> • detail information resources to guide informed consent under written information to be given to individual, parent or carer • include updated administration advice for those with stable and unstable bleeding disorders, in line with other UKHSA PGD templates • include updated information from the Revaxis[®] SPC, including that excipients contain phenylalanine. Reference to NSPKU advice that the amount contained in vaccines is negligible and vaccination should proceed • clarify all valid indications on the PGD cover page and in the clinical condition or situation to which this PGD applies • update associated references <p>Reviewed to include minor rewording of standard text, layout and formatting changes for clarity and consistency with other PTHB PGDs. Include reference to use in PTHB Occupational Health Service.</p>	
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This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA Td/IPV (Revaxis[®]) PGD template v6.00 developed by the following 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 Committee).

The UKHSA template has been adapted for use in PTHB.

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

Developed By:	Name
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA
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Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant - Immunisation and Vaccine Preventable Diseases Division, UKHSA

Expert panel

Name	Designation
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Specialist Pharmacist, Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Michelle Jones	Principle Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board (ICB)
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Elizabeth Lockett	Senior Screening and Immunisation Manager, NHSE South West
Dr 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
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London

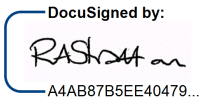
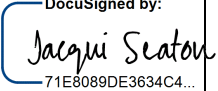
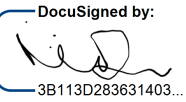
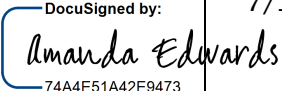
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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr Richard Stratton	Lead doctor for PTHB		7/17/2024
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB		7/17/2024
Senior representative of professional group using the PGD Marie Davies	Deputy Director of Nursing for PTHB		7/17/2024
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement		7/17/2024

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.

[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](#).**

¹ This includes any relevant amendments to legislation

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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 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.

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.

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

1. Characteristics of staff

<p>Qualifications and professional registration</p>	<p>Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> • 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) <p>The practitioners above must also fulfil the Additional requirements detailed below.</p> <p>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.</p>
<p>Additional requirements</p>	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • 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 eLfh PGD eLearning programme, PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). Individuals operating under this PGD must be assessed as competent (see Appendix A) • 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

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	<p>contact PTHB Immunisation coordinator for further information.</p> <ul style="list-style-type: none"> • 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 (also available via ESR) • must be familiar with the All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Basic Life Support skills • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
<p>Continued training requirements</p>	<p>Updating at least every 2 years on the administration of low-dose diphtheria, tetanus and inactivated poliomyelitis vaccine (Td/IPV) vaccine.</p> <p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).</p> <p>Practitioners must make a self-declaration of competency on PADR (if relevant). The personal development plan (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning.</p> <p>Compliance with all mandatory NHS training (if relevant).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and the UKHSA, NHSE and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be</p>

	<p>required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p> <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.</p> <p>If used in PTHB Occupational Health Service, must be used in line with PTHB Occupational Health Immunisation policy.</p>
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2. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<p>Indicated for:</p> <ul style="list-style-type: none"> • the active immunisation of individuals from 10 years of age for the prevention of diphtheria, tetanus and poliomyelitis, in accordance with the national immunisation programme and recommendations given in Chapter 15, Chapter 26 and Chapter 30 of Immunisation Against Infectious Disease: the Green Book. • individuals who require immunisation in response to an outbreak of polio in accordance with the National polio guidelines: Local and regional services guidelines and recommendations from the local health protection team • individuals requiring immunisation in line with Diphtheria: public health control and management of diphtheria in England guidance • individuals with a tetanus prone wound requiring management in line with recommendations in Chapter 30 of the Green Book • individuals requiring protection in accordance with NaTHNaC against diphtheria, tetanus or polio for travel purposes to areas where such diseases are epidemic or endemic <p>If used in PTHB Occupational Health Service, the PGD must be used in line with PTHB Occupational Health Immunisation policy.</p> <p>It is the responsibility of the administering healthcare professional to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the vaccination. If there is any reason for concern, seek medical advice.</p>
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<p>Criteria for inclusion</p>	<p>Individuals aged 10 years and over who:</p> <ul style="list-style-type: none"> • require a booster following a primary course of immunisation against diphtheria, tetanus and poliomyelitis (this booster is usually offered at 13 to 18 years of age, unless the course has already been completed) • have no history or an incomplete history of diphtheria, tetanus or poliomyelitis immunisation • in accordance with NaTHNaC, are travelling to an area where medical attention may not be accessible should a tetanus prone wound occur, or will be residing in epidemic or endemic areas where tetanus, diphtheria or poliomyelitis protection is required and the final dose of the relevant antigen was received more than 10 years ago, even if the individual has received 5 doses of tetanus-containing vaccine previously • have a tetanus prone wound and one or more of the following apply (see Green Book Chapter 30): <ul style="list-style-type: none"> ○ primary tetanus immunisation is incomplete ○ tetanus boosters are not up to date or last dose of tetanus containing vaccine was more than 10 years ago ○ tetanus immunisation status is unknown or uncertain ○ individual has never received tetanus immunisation • require vaccination in line with recommendations for the management of cases and contacts of diphtheria <p>Management of cases and contacts of polio in an outbreak</p> <p>Individuals 6 years and over who require vaccination in line with the management of cases and contacts of polio in an outbreak in accordance with the National polio guidelines: Local and regional services and recommendations from the local health protection team, where dTaP/IPV (Boostrix-IPV® or Repevax®) is not available or Td/IPV is recommended by an Outbreak Control Team. See special considerations and additional information section and the dTaP/IPV PGD 0073.</p> <ul style="list-style-type: none"> • Medical and drug history taken, no reason for exclusion • Informed consent, from the individual or a person legally able to act on the individual’s behalf, must be obtained prior to administration <p>NB. Refer to PTHB Consent to Treatment and Examination Policy</p>
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	<p>Any vulnerable adult or child protection concerns should be referred to Safeguarding PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advise from the local Safeguarding team should be sought (see below).</p>
<p>Criteria for exclusion (Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)</p>	<p>Individuals who have not given valid consent (or for whom a 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, parent or carer section).</p> <p>Refer to sections "Action to be taken if the individual is excluded" and "Action to be taken if the individual, parent or carer declines treatment".</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are aged less than 10 years, except for individuals of aged 6 years and over for the management of polio in an outbreak in accordance with the National polio guidelines: Local and regional services and recommendations from the local health protection team • have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus 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, including neomycin, streptomycin or polymyxin B • are suffering from acute severe febrile illness. The presence of a minor infection is not a contraindication for immunisation
<p>Cautions including any relevant action to be taken</p>	<p>Facilities for management of anaphylaxis should be available at all vaccination premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK).</p> <p>Td/IPV may be given to pregnant women when protection is required without delay, such as following a tetanus prone wound or in management of outbreaks of diphtheria or poliomyelitis. However, pregnant women from week 16 of pregnancy onwards should instead be protected by the administration of the routinely indicated Tdap or dTaP/IPV (see Pertussis PGD0072).</p>

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of preventable infection, and vaccination should be promptly given once the diagnosis is clear, the expected course of the condition is known, or both.

The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Where possible, vaccination should be postponed until immune function has recovered. However, vaccination of subjects with chronic immunodeficiency, such as AIDS, is still recommended even if the antibody response might be limited. 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. Revaxis[®] contains approximately 10 micrograms of phenylalanine per 0.5ml dose. Though phenylalanine may be harmful to individuals with phenylketonuria (PKU), the parent or carer of the individual will be well versed as to the amounts of phenylalanine tolerable in their diet. The National Society for Phenylketonuria (NSPKU) advise the amount of phenylalanine contained in vaccines is negligible and therefore strongly advise individuals with PKU to take up the offer of immunisation.

Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to [BNF/SPC](#) for full list)

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

	<p>and</p> <ul style="list-style-type: none"> • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 <p>Advice can also be sought from local Safeguarding leads</p>
<p>Action to be taken if the individual is excluded</p>	<p>If aged under 10 years, assess for immunisation with either DTaP/IPV/Hib/HepB (PGD0141) or dTaP/IPV (PGD0073) as appropriate.</p> <p>In case of postponement due to acute febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team, PTHB Infection Prevention and Control team or the individual’s clinician as appropriate (rather than delay immunisation). The risk to the individual of not being immunised must be taken into account.</p> <p>Explain reason to patient / carer.</p> <p>Document the reason for exclusion and any action taken in the individual’s clinical records.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p> <p>For PTHB occupational Health Service- refer to Occupational Health Consultant as necessary and document advice given in the individual’s occupational health records</p>
<p>Action to be taken if the individual, parent or carer declines treatment</p>	<p>Informed consent, from the individual or a person legally able to act on the person’s behalf, must be obtained for each administration and recorded appropriately. The Patient information leaflet (PIL) for the vaccine 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.</p> <p>Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.</p> <p>Document advice given and the decision reached.</p>

	<p>Inform the Child Health department if appropriate – if any vaccination is declined for a child under 19 years, Child Health must be informed and appropriate form completed. Where appropriate, inform the GP using the local agreed system.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p> <p>For PTHB occupational Health Service- refer to Occupational Health Consultant as necessary and document advice given in the individual’s occupational health records</p>
Arrangements for referral for medical advice	<p>Refer to GP, paediatrician or consultant in communicable disease control (CCDC) or the PTHB occupational health consultant for clinical advice as necessary.</p> <p>Document any advice given.</p>

3. Description of treatment

Name, strength and formulation of drug	<p>Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV):</p> <ul style="list-style-type: none"> • Revaxis®, suspension for injection in a pre-filled syringe
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	<p>Primary immunisation is off-label administration in accordance with the recommendations given for individuals over 10 years of age in Chapter 15, Chapter 26 and Chapter 30 of Immunisation Against Infectious Disease: the Green Book.</p> <p>Administration to individuals who have received a vaccine containing diphtheria or tetanus toxoids within the previous 5 years is off-label but indicated for the management of primary immunisation (as above) and for cases and contacts of diphtheria or polio in accordance with disease management guidelines (see Dose and frequency of administration).</p> <p>Administration to individuals who experienced neurological complications following an earlier immunisation against either diphtheria or tetanus (or both) is off-label but may proceed once the cause is identified, the condition has</p>

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	<p>been stabilised or the expected course of the condition becomes clear in accordance with the recommendations in Chapter 15 and Chapter 30 of Immunisation Against Infectious Disease: the Green Book.</p> <p>The SPC does not make reference to the use of Td/IPV (Revaxis®) for the management of cases or contacts of an outbreak, but does include use of the vaccine as a booster and states 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 the National polio guidelines: Local and regional services.</p> <p>The SPC does not recommend the use of Revaxis® to be administered to individuals who completed a primary vaccination course or received a booster of a vaccine containing diphtheria or tetanus toxoids within the previous 5 years. In an outbreak, the vaccine would still be given to an eligible individual at risk, in accordance with the relevant national guidance and Chapter 26.</p> <p>The SPC states there are no clinical data available regarding the use of Revaxis® in individuals with an incomplete, or no history of a primary series of diphtheria and tetanus toxoids or of vaccinations against poliomyelitis, however, the vaccine is given in accordance with the relevant Green Book chapters.</p> <p>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 the All Wales Advisory document on Ordering Storage and Handling of Vaccines and 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.</p> <p>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 outside of product license but in accordance with national guidance.</p>
<p>Route and method of administration</p>	<p>Administer by intramuscular injection, preferably into the deltoid muscle of the upper arm. See Green book chapter 4.</p>

When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given into 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.

Individuals with bleeding disorders may be vaccinated intramuscularly, if in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be given with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or other treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection. If the intramuscular route is not considered suitable, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection instead, in accordance with the recommendations in the Green Book [Chapter 4](#).

The vaccine's normal appearance is a cloudy white suspension that may sediment during storage. Shake the pre-filled syringe well to distribute uniformly the suspension before administering the vaccine.

The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and discard the vaccine in accordance with local procedures.

The vaccine [SPC](#) provides further guidance on preparation and administration.

<p>Dose and frequency of administration</p>	<p>Single 0.5ml dose per administration</p> <p>Routine childhood immunisation schedule Td/IPV is routinely offered to teenagers as a second booster dose at around 14 years of age. It should ideally be given 10 years after the first booster dose. It should be given at the school session or scheduled appointment provided a minimum of 5 years have elapsed between the first and second boosters.</p> <p>Note: the first booster is usually given at pre-school age using dTaP/IPV (Repevax[®] or Boostrix[®]-IPV). Historically, DTaP/IPV (Infanrix[®]-IPV) has also been used.</p> <p>UK immunisation schedule for previously unimmunised individuals or where there is an unknown or incomplete history of diphtheria, tetanus and poliomyelitis vaccination Infants with uncertain or incomplete diphtheria, tetanus and poliomyelitis vaccine history should be vaccinated in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart.</p> <p>The primary course consists of 3 doses, allowing an interval of one month between doses. Where a primary course is interrupted it should be resumed but not repeated.</p> <p>A first booster dose should be administered at least 5 years after the third dose of the primary course.</p> <p>A second booster dose should be administered a minimum of 5 years and ideally 10 years after the first booster dose, if less than 5 doses of diphtheria, tetanus and polio vaccine are documented.</p> <p>Travel immunisation Where recommended in NaTHNaC, individuals travelling should be vaccinated in accordance with the UK schedule. A single booster dose may be indicated for fully immunised individuals whose last dose of vaccine was more than 10 years ago.</p> <p>Management of tetanus prone wounds Individuals with a tetanus prone wound who received their last dose of tetanus-containing vaccine more than 10 years ago should receive a reinforcing dose of vaccine.</p>
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	<p>Individuals with incomplete or uncertain history of tetanus immunisation should be vaccinated in accordance with the recommendations in the Green Book Chapter 30 Table 30.1.</p> <p>Individuals may also require human tetanus immunoglobulin (see Green Book Chapter 30). Administration of tetanus immunoglobulin is not covered by this PGD.</p> <p>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 (England 2023) guidelines and recommendations from the local health protection team.</p> <p>Individuals should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes.</p> <p>Unimmunised individuals should receive 3 doses at monthly intervals.</p> <p>Individuals who are fully immunised but have not received diphtheria-containing vaccine in last 12 months may be given a single reinforcing dose of Td/IPV.</p> <p>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 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.</p> <p>Individuals should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes.</p>
Duration of treatment	See Dose and frequency of administration
Quantity to be administered	Single 0.5 ml 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.

	<p>Vaccines for the school programmes are ordered as per local policy and arrangement. Contact PTHB Medicines Management Department for details.</p> <p>Vaccine for indications other than the national immunisation programme should be obtained from manufacturers or their wholesalers.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.</p>
<p>Storage</p>	<p>Store at +2°C to +8°C. Store in original packaging to protect from light. Do not freeze.</p> <p>Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage.</p> <p>See 'MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP' for details of actions required in the event of a fridge temperature excursion.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance.</p> <p>Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.</p> <p>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 PTHB Datix reporting system Once for Wales Reporting System.</p>
<p>Disposal</p>	<p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local authority arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste and</p>

	<p>guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.</p>
<p>Drug interactions</p>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended for eligible individuals, even if the antibody response may be limited. This is not a reason to withhold vaccination and the individual, parent or carer should be advised of this.</p> <p>May be given at the same time as other vaccines.</p> <p>A detailed list of drug interactions is available from the vaccine's SPC.</p>
<p>Identification and management of adverse reactions</p>	<p>Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the injection site.</p> <p>Common adverse reactions include pyrexia, headache, vertigo, nausea and vomiting.</p> <p>Allergic reactions can occur including generalised skin reactions such as urticaria, anaphylactic reactions, angioedema and shock.</p> <p>In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use:</p> <p>Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone.</p> <p>In case of anaphylaxis:</p> <ul style="list-style-type: none"> • Refer to adrenaline (epinephrine) 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 low-dose diphtheria, tetanus and inactivated poliomyelitis vaccine (Td/IPV) • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system <p>This list is not exhaustive. A detailed list of adverse reactions is available from the vaccine's SPC.</p>

	<p>Report any suspected adverse reactions to a doctor.</p>
<p>Reporting procedure of adverse reactions</p>	<p>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.</p> <p>Any adverse reaction to a vaccine should be documented in the individual’s record and the individual’s GP should be informed.</p> <p>All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.</p>
<p>Written information to be given to individual, parent or carer</p>	<p>Offer marketing authorisation holder’s patient information leaflet (PIL) provided with the vaccine.</p> <p>For resources in accessible formats and alternative languages, please visit Home-Health Publications.</p> <p>Immunisation promotional material may be provided as appropriate:</p> <ul style="list-style-type: none"> • a guide to the 3 in 1 teenage booster (Td/IPV) vaccine leaflet • travelling abroad to visit friends and relatives leaflet • diphtheria warn and inform letter (including factsheet) <p>Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC.</p> <p>Further information for printing and website links suitable for patients can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources.</p>
<p>Advice and follow up treatment</p>	<p>Inform the individual, parent or carer of possible side effects and their management.</p> <p>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.</p>

	<p>When administration is postponed or a subsequent dose is due, advise the individual, parent or carer when to return for vaccination.</p>
<p>Special considerations and additional information</p>	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a working telephone at the time of vaccination.</p> <p>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.</p> <p>A family history of seizures is not a contraindication to immunisation (see Green Book Chapter 26 and the SPC). When there is a personal or family history of febrile seizures, there is an increased risk of these occurring after any fever, including that caused by immunisation. Seizures associated with fever are rare in the first 6 months of life and most common in the second year of life. After this age, the frequency falls and they are rare after 5 years of age (see Green Book Chapter 26).</p> <p>Children coming to the UK who have a history of completing immunisation in their country of origin may not have been offered protection against all the antigens currently used in the UK. 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 individuals are unimmunised and the full UK recommendations should be followed.</p> <p>Where children have had a fourth dose of tetanus, diphtheria and polio-containing vaccine at around 18 months of age, this dose should be discounted as it may not provide satisfactory protection until the time of the teenage booster. The routine pre-school and subsequent boosters should be given according to the Wales schedule. When given as a 3-in-one booster to Year 9 pupils, this represents a good opportunity for providers to check the individual is also up to date with other routine vaccines, including MenACWY (PGD0094), HPV (PGD0060) and MMR (PGD0163) vaccines. Provided each vaccine is given at a different administration site, all of these vaccines may be co-administered together.</p>

	<p>If a person attends for a routine booster dose and has a history of receiving a vaccine following a tetanus-prone wound, attempts should be made to identify which vaccine was given. If the vaccine given at the time of the injury was the same as that due at the current visit and was given after an appropriate interval, then the routine booster dose is not required. Otherwise, the dose given at the time of injury should be discounted as it may not provide long-term protection against all antigens, and the scheduled immunisation should be given. Such additional doses are unlikely to produce an unacceptable rate of reactions.</p> <p>If Tdap (ADACEL®) vaccine is administered in error instead of Td/IPV as a Year 9 booster, the child should be offered Td/IPV as soon as the error is realised, as Tdap does not provide protection against polio. Healthcare practitioners should familiarise themselves with the difference between the vaccines and their packaging to minimise a recurrence. Where possible and applicable, ADACEL® should be kept in a separate part of the vaccine fridge.</p> <p>People who inject drugs (PWID) are at greater risk of tetanus. Every opportunity should be taken to ensure that they are fully protected against tetanus. Booster doses should be given if there is any doubt about their immunisation status.</p>
<p>Records</p>	<p>Record consultation details as required by local procedures. The practitioner must ensure the following is recorded:</p> <ul style="list-style-type: none"> • 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. Record name of representative who gave consent if appropriate. • name of individual, address, date of birth and GP with whom the individual is registered • medical and drug history taken, including any allergies and previous adverse events • printed name and signature of immuniser • 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 the individual is excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered via PGD, record PGD title and version number

Records should be signed and dated (or password-controlled 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 or pathway as required by any local or contractual arrangement. If a vaccine is administered to a child up to 19 years of age, forward a notification of vaccination given to Child Health Department using the appropriate documentation/pathway as required by any local or contractual arrangement (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	<p>Td/IPV vaccine (Revaxis®)</p> <ul style="list-style-type: none"> • Immunisation against infectious disease: The Green Book Chapter 15, Chapter 26, updated 19 April 2013 and Chapter 30 updated 6 June 2022. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of product characteristic for Revaxis®, Sanofi Pasteur, updated 23 June 2023 https://www.medicines.org.uk/emc/product/5581 • Vaccination of individuals with uncertain or incomplete immunisation status, updated 6 September 2023. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status • Public health control and management of diphtheria in England: 2023 guidelines, updated 9 November 2023 https://www.gov.uk/government/publications/diphtheria-a-public-health-control-and-management-in-england-and-wales • National polio guidelines: Local and regional services, updated 26 September 2019 https://www.gov.uk/government/publications/polio-national-guidelines • The National Society for Phenylketonuria (NSPKU) Medical Advisory Panel: vaccines and PKU, issued 31 January 2023 https://nspku.org/download/vaccines-and-pku/ <p>General</p> <ul style="list-style-type: none"> • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01/ • 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 • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018
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Reference Number: PGD 0182B

Valid from: 04/08/2024

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Expiry Date: 04/12/2026

	<p>https://www.nice.org.uk/guidance/mpg2/resources</p> <ul style="list-style-type: none">• UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation• Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors• 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. 2013
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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 must 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	Signature of senior representative authorising health professional	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.