UK Health Security Agency

Publications gateway number: GOV-16527

Low-dose diphtheria, tetanus and inactivated poliomyelitis vaccine (Td/IPV) Patient Group Direction (PGD)

This PGD is 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 in England. 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. The PGD may also be used for individuals travelling to high-risk areas.

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

Reference no:	Td/IPV (Revaxis®) PGD
Version no:	v6.00
Valid from:	4 August 2024
Review date:	4 August 2026
Expiry date:	4 December 2026

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly-funded immunisation in England in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 (Characteristics of staff). **Sections 2 and 7 can be amended within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance of the NHS organisations using the PGD. The fields in sections 2 and 7 cannot be used to alter, amend or add to the clinical contents. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

[1] This includes any relevant amendments to legislation.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Current versions of UKHSA PGD templates for authorisation can be found from: Immunisation patient group direction (PGD) templates

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Vaccination Team, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

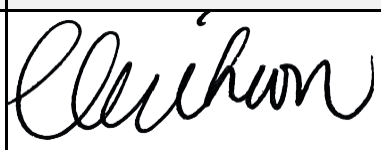
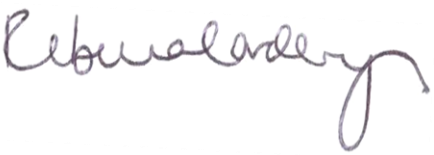
- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

Change history

Version	Change details	Date
v1.00 and v2.00	See earlier versions of this PGD for details of change history	16 October 2015 to 29 September 2017
v3.00	Td/IPV (Revaxis®) PGD routine review and amended to: • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	12 September 2019
v4.00	Td/IPV (Revaxis®) PGD routine review and amended to: • rebrand from PHE to UKHSA • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates	20 October 2021
v5.00	Td/IPV (Revaxis®) PGD reviewed and amended to: • 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 into UK where history of immunisation is not known and children with partial and unknown history of immunisation as per Green Book Chapter 26 and the SPC in the special consideration and additional information section	5 August 2022
v6.00	Td/IPV (Revaxis®) PGD amended to: • 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, diphtheria, polio or tetanus and where resolution of symptoms took longer than 7 days, in line with Chapter 30 of the Green Book • 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	4 July 2024

1. PGD development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		2 July 2024
Doctor	Dr Rebecca Cordery Consultant Epidemiologist - Immunisation and Vaccine Preventable Diseases Division, UKHSA		2 July 2024
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant - Immunisation and Vaccine Preventable Diseases Division, UKHSA		2 July 2024

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

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 Luckett	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

2. Organisational authorisations

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

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England - Midlands authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Primary care services and/or all organisations commissioned or contracted by NHS England – Midlands to provide immunisation services in: • Derby and Derbyshire • Lincolnshire • Leicester, Leicestershire, and Rutland • Northamptonshire • Nottingham and Nottinghamshire • Herefordshire and Worcestershire • Birmingham and Solihull • Staffordshire and Stoke-on-Trent • Shropshire, Telford, and Wrekin • Black Country • Coventry and Warwickshire
Limitations to authorisation
None.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Regional Director of Commissioning Integration – NHSE - Midlands	Roz Lindridge		08/07/2024

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to Vaccination Team, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

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

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for: • the active immunisation of individuals from 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

Criteria for inclusion	Individuals aged 10 years and over who:
	• 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):
	  ○ 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
	Management of cases and contacts of polio in an outbreak
	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.

Criteria for exclusion[2] (continued over page)	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

[2] 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

Criteria for exclusion (continued)	available to inform consent (see written information to be given to individual, parent or carer section). Individuals who: • 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
Cautions including any relevant action to be taken	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). 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 PGD). 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.
Action to be taken if the individual is excluded (continued over page)	If aged under 10 years, assess for immunisation with either DTaP/IPV/Hib/HepB or dTaP/IPV PGDs as appropriate. 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. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as appropriate (rather than delay immunisation).

Action to be taken if the individual is excluded (continued)	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, parent or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of the Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV): • Revaxis®, suspension for injection in a pre-filled syringe.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	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. 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). 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 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. 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. 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. 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. Vaccines should be stored according to the conditions detailed in the storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to Vaccine Incident Guidance. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD. 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 licence but in accordance with national guidance.
Route and method of administration (continued over page)	Administer by intramuscular injection, preferably into the deltoid muscle of the upper arm. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably into different limbs. If given into

Route and method of administration (continued)	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.
Dose and frequency of administration (continued over page)	Single 0.5ml dose per administration **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. **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. **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. 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. A first booster dose should be administered at least 5 years after the third dose of the primary course. 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. **Travel immunisation** Where recommended in NaTHNaC, individuals travelling should be vaccinated in accordance with the UK schedule.

Dose and frequency of administration (continued)	A single booster dose may be indicated for fully immunised individuals whose last dose of vaccine was more than 10 years ago. **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. 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. Individuals may also require human tetanus immunoglobulin (see Green Book 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 (England 2023) guidelines and recommendations from the local health protection team. Individuals should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes. Unimmunised individuals should receive 3 doses at monthly intervals. Individuals who are fully immunised but have not received diphtheria-containing vaccine in the last 12 months may be given a single reinforcing dose of Td/IPV. **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. Individuals should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes.
Duration of treatment	See dose and frequency of administration
Quantity to be supplied and administered	Single 0.5ml dose per administration.
Supplies	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge. Vaccine for indications other than the national immunisation programme should be obtained from manufacturers or their wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Storage (continued over page)	Store at +2°C to +8°C. Store in original packaging to protect from light. Do not freeze. 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

Storage (continued)	risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local authority arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended for eligible individuals, even if the antibody response may be limited. This is not a reason to withhold vaccination and the individual, parent or carer should be advised of this. May be given at the same time as other vaccines. A detailed list of drug interactions is available from the vaccine's SPC.
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 pyrexia, headache, vertigo, nausea and vomiting. Allergic reactions can occur including generalised skin reactions such as urticaria, anaphylactic reactions, angioedema and shock. A detailed list of adverse reactions is available from the vaccine's SPC.
Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to individual, parent or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. For resources in accessible formats and alternative languages, please visit Home-Health Publications. Immunisation promotional material may be provided as appropriate: • 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) 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.
Advice and follow up treatment	Inform the individual, parent or carer of possible side effects and their management. 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. When administration is postponed or a subsequent dose is due, advise the individual, parent or carer when to return for vaccination.

Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine)1 in 1,000 injection and access to a telephone at the time of vaccination. 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. 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). 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. 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 UK 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, HPV and MMR vaccines. Provided each vaccine is given at a different administration site, all of these vaccines may be co-administered together. 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. 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. 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.
Records (continued over page)	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 • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered

Records (continued)	• 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 • supplied via PGD 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 the 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. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Td/IPV vaccine (Revaxis®)** • 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-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/ **General** • 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-htm-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, updated 27 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 www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

Td/IPV (Revaxis®) PGD v6.00 Valid from: 4 August 2024 Expiry: 4 December 2026

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **insert name of organisation** for the above-named healthcare professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.