



Publications gateway number: GOV-12925

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, in accordance with the national immunisation programme in England, for travel. This PGD is also used for the administration of Td/IPV vaccine for the management of cases and contacts of diphtheria and poliomyelitis in an outbreak according to the national guidelines, recommendations from the JCVI and from the local health protection teams.

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: v5.00
Valid from: 5 August 2022
Review date: 5 March 2024
Expiry date: 4 August 2024

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

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

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided.

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

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

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

Current versions of UKHSA PGD templates for authorisation can be found from: [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: Contacts listed on page 4 and 5 of this PGD




¹ This includes any relevant amendments to legislation.

Change history

Version	Change details	Date
V01.00	New PHE PGD template	16 October 2015
V02.00	Td/IPV (Revaxis®) PGD routine review and amended to: <ul style="list-style-type: none"> • include vaccination in line with recommendations for the management of diphtheria or polio • remove exclusions regarding timing of previous vaccination (see dose section for schedules) • remove exclusions relating to neurological conditions, encephalopathy and Guillain Barre/brachial neuritis and relevant advice moved to the cautions section • update off-label section in relation to amended indications • update dose section with management of cases and contacts of polio and diphtheria • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	29 September 2017
V03.00	Td/IPV (Revaxis®) PGD routine review and amended to: <ul style="list-style-type: none"> • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	12 September 2019
V04.00	Td/IPV (Revaxis®) PGD 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 	20 October 2021
V5.00	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 	5 August 2022

1. PGD development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		5 August 2022
Doctor	Dr Gayatri Amirthalingam Consultant Epidemiologist - Immunisation and Countermeasures, National Infection Service, UKHSA		5 August 2022
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Vaccine Preventable Diseases Division, UKHSA		5 August 2022

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been approved by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

Expert Panel

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


2. Organisational authorisations



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

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

NHSE North East and Yorkshire authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
NHS England (NHSE) commissioned immunisation services or NHS Trust providing immunisation services.
Limitations to authorisation
Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations/providers commissioned by NHSE North East and Yorkshire (NEY) to deliver immunisation programmes within the whole of the NHSE region of North East and Yorkshire

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Assistant Medical Director and Responsible Officer, NHS England –NEY	Dr James Gossow		10 th August 2022

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date
NHSE NEY PGD Governance assurance review (Medicines Optimisation Pharmacist Lead, NHS NECS)	Kurt Ramsden		8 th August 2022
Screening and Immunisation Coordinator Specialist Community Public Health Nurse – SN	Wendy Watson		10 th August 2022

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation teams. See area-specific contacts below:

For North East and North Cumbria Area (i.e. Northumberland, Tyne & Wear, Durham Darlington and Tees and North Cumbria) use the following:

NHS England Screening and Immunisation Team: email
england.cane.screeningimms@nhs.net or NECS Medicine Optimisation Pharmacists: Kurt
Ramsden: kurtramsden@nhs.net or Sue White: sue.white14@nhs.net

Please note - All North East and North Cumbria PGDs can be found at:

<https://medicines.necsu.nhs.uk/resources/patient-group-directions/>

For Yorkshire and Humber Area use the following:

West Yorkshire - england.wysit@nhs.net

South Yorkshire and Bassetlaw - england.sybsit@nhs.net

North Yorkshire and Humber ENGLAND.NYAHSIT@nhs.net or the Health Protection Team
Acute Response Centre (ARC): Contact Number: 0113 3860 300.

Please note - All Yorkshire and Humber PGDs can be found at:

<https://www.england.nhs.uk/north-east-yorkshire/our-work/information-for-professionals/pgds/>

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	<p>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 Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
Additional requirements	<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 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 <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
Continued training requirements	<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 should be constantly alert to any subsequent recommendations from the UKHSA and/or 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 required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p>

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	<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
Criteria for inclusion	<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 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 guidelines and recommendations from the local health protection team.</p>
Criteria for exclusion² Continued over page	<p>Individuals for whom no valid consent has been received.</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 guidelines 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

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)	<p>conjugate vaccines where diphtheria or tetanus toxoid is used in the conjugate</p> <ul style="list-style-type: none"> • 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	<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 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 the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.</p> <p>If a child has experienced encephalopathy or encephalitis within seven days of immunisation, it is unlikely that these conditions will have been caused by the vaccine and they should be investigated by a specialist. If a cause is identified or the child recovered within seven days, immunisation should proceed as recommended. In children where no underlying cause was found, and the child did not recover completely within seven days, immunisation should be deferred until the condition has stabilized or the expected course of the condition becomes clear.</p> <p>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 recommended even if the antibody response might be limited.</p>
Action to be taken if the patient is excluded	<p>If aged under 10 years assess for immunisation with DTaP/IPV/Hib/HepB, DTaP/IPV or dTaP/IPV as appropriate.</p> <p>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as appropriate.</p> <p>The risk to the individual of not being immunised must be taken into account.</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>
Action to be taken if the patient or carer declines treatment Continued over page	<p>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'.</p>

Action to be taken if the patient or carer declines treatment (continued)	Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral	As per local policy

5. 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 five 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 diphtheria and/or tetanus is off-label but may proceed once the cause is identified, the condition has been stabilized 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 outbreak, cases or contacts 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 guidelines.</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 five years, however, in an outbreak the vaccine would be given in accordance with the national guidance given in response to the outbreak 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>Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine</p>
Continued over page	

Off-label use (continued)	is being offered in accordance with national guidance but that this is outside the product licence.
Route and method of administration	<p>Administer by intramuscular injection, preferably into deltoid region of the upper arm.</p> <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.</p> <p>The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in 'The Green Book' Chapter 4.</p> <p>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.</p> <p>The vaccine should not be used if foreign particles are present in the suspension.</p> <p>The SPC provides further guidance on administration.</p>
Dose and frequency of administration	<p>Single 0.5ml dose per administration</p> <p>Routine childhood immunisation schedule</p> <p>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) or historically using DTaP/IPV (Infanrix®-IPV)).</p> <p>UK immunisation schedule for previously unimmunised individuals or where there is an unknown or incomplete history of diphtheria, tetanus and poliomyelitis vaccination</p> <p>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 three 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, 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</p> <p>Individuals travelling should be vaccinated in accordance with the UK schedule.</p>
Continued over page	

<p>Dose and frequency of administration (continued)</p>	<p>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</p> <p>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> <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</p> <p>Cases and contacts of diphtheria should be managed in accordance with Public health control and management of diphtheria (in England and Wales) guidelines and recommendations from the local health protection team.</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 three 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</p> <p>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.</p> <p>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>
<p>Duration of treatment</p>	<p>See Dose and frequency of administration</p>
<p>Quantity to be supplied and administered</p>	<p>Single 0.5ml dose per administration.</p>
<p>Supplies</p>	<p>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> <p>Vaccine for indications other than the national immunisation programme should be obtained from manufacturers/wholesalers.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3 and Protocol for ordering storage and handling of vaccines).</p>

Storage	<p>Store at +2°C to +8°C. Store in original packaging to protect from light. Do not freeze.</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 for suitability of continued off-label use or appropriate disposal, refer to Vaccine Incident Guidance.</p>
Disposal	<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 guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).</p>
Drug interactions	<p>Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p>May be given at the same time as other vaccines.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website.</p>
Identification and management of adverse reactions	<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>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website.</p>
Reporting procedure of adverse reactions	<p>Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store.</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>
Written information to be given to patient or carer	<p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p>
Patient advice and follow up treatment	<p>Inform the individual/parent/carer of possible side effects and their management.</p> <p>The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>When administration is postponed advise the individual/parent/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 1000 injection and access to a 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 SPCs). 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 six months of life and most common in the second year of life. After this age the frequency falls and they are rare after five 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 UK schedule.</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>Intravenous drug users 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>Continued over page</p>	<p>Record:</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 • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date

Records (continued)	<ul style="list-style-type: none"> • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD <p>Records should be signed and dated (or a password-controlled immuniser's record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
-------------------------------	---

6. 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 Immunisation against infectious disease - GOV.UK Summary of product characteristic for Revaxis®, Sanofi Pasteur. 24 July 2020. REVAXIS - Summary of Product Characteristics (SmPC) Vaccination of individuals with uncertain or incomplete immunisation status. Updated 17 March 2022. Vaccination of individuals with uncertain or incomplete immunisation status - GOV.UK Public health control and management of diphtheria (in England and Wales) guidelines. Published 21 June 2022. Diphtheria: public health control and management in England - GOV.UK National polio guidelines: Local and regional services. Published 26 September 2019. Polio: national guidelines - GOV.UK <p>General</p> <ul style="list-style-type: none"> Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. NHS England » (HTM 07-01) Management and disposal of healthcare waste National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. Immunisation training standards for healthcare practitioners - GOV.UK NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. Overview Patient group directions Guidance NICE NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. www.nice.org.uk/guidance/mpg2/resources UKHSA Immunisation Collection www.gov.uk/government/collections/immunisation Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors
----------------	---

7. Practitioner authorisation sheet

Td/IPV (Revaxis®) PGD v5.00 Valid from: 5 August 2022 Expiry: 4 August 2024

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.