

Gibraltar Health Authority



PATIENT GROUP DIRECTION

Issued Under Part 2 of the Medicines (Prescriptions Only) Regulations, 1987 by the
Director of Public Health with the consent of the Minister

for

Diphtheria, tetanus and inactivated poliomyelitis vaccine (TD/IPV-Revaxis)

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority (GHA) St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	11 th April 2025		
Date of expiry	11 th April 2027		
Staff characteristics	See below (section 1)		
Professional Authorisation		SIGNATURE	DATE
Lead Doctor	Dr Helen Carter Director of Public Health ¹		
In Consultation with		SIGNATURE	DATE
Lead Pharmacist	Ms Melanie Gordon Chief Pharmacist		
Lead Nurse	Ms Sandra Gracia Director of Nursing		
Legal Authorisation		SIGNATURE	DATE
With the consent of Minister	The Honourable Minister for ² Health Gemma Arias- Vasquez MP		

¹ A Patient Group Direction issued shall only have effect if it is signed by the Director of Public Health with the consent of the Minister.

² See footnote 1.

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• Revaxis®, suspension for injection in a pre-filled syringe. Valid from: 11th April 2025 Expiry: 11th April 2027

Authors: Dr Helen Carter DPH and Ian Bramble EN

1. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: <ul style="list-style-type: none"> nurses or midwives currently registered with the Gibraltar Nursing Registration Board (NRB) practitioners currently registered with the Gibraltar Medical Registration Board (GMRB) Anyone deemed by the Director of Public Health to be competent who meets the additional requirements below.
Additional requirements	Additionally, practitioners: <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 assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016) and to discuss issues related to vaccination must be competent in the correct 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

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	THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT
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 GHA, UKHSA and/or NHS England and NHS Improvement 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>

2. 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 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
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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 • 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"> o primary tetanus immunisation is incomplete o tetanus boosters are not up to date or last dose of tetanus containing vaccine was more than 10 years ago o tetanus immunisation status is unknown or uncertain o 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. <u>See special considerations and additional information section</u> and the dTaP/IPV PGD.</p> <p>In an outbreak situation, under written instruction from the Director of Public Health, specific additional groups of the population may be offered an inactivated seasonal influenza vaccine as specified in the written instruction.</p>
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Criteria for exclusion³	<p>Individuals for whom valid consent, or ‘best-interests’ decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016, has</p>
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³ 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

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	<p>not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). The Patient information leaflet (PIL) for Spikevax Bivalent (original/omicron) should be available to inform consent.</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 PGD).</p> <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.</p> <p>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Where possible, vaccination</p>

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	<p>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.</p> <p>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.</p> <p>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.</p>
Action to be taken if the patient is excluded	<p>If aged under 10 years, assess for immunisation with either DTaP/IPV/Hib/HepB or dTaP/IPV PGDs 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 Director of Public Health or the individual's clinician as appropriate (rather than delay immunisation).</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	<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. Where a person lacks the capacity, in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016, 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/carers about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Document advice given and the decision reached</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p>
Arrangements for referral for medical advice	As per local GHA policy

3. Description of treatment

Name, strength & 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

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<p>Off-label use</p>	<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 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</p>
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	<p>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.</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 licence but in accordance with national guidance.</p>
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Route / method of administration	<p>Administer by intramuscular injection, preferably into the deltoid muscle 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. The vaccines should be given at separate sites, preferably into 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.</p> <p>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.</p> <p>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.</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 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.</p> <p>The vaccine SPC provides further guidance on preparation and 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</p>

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<p>Dose and frequency of administration (continued)</p>	<p>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</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 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</p> <p>Where recommended in NaTHNaC, individuals travelling should be vaccinated in accordance with the GHA schedule.</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 tetanuscontaining 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>
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<p>Dose and frequency of administration (continued)</p>	<p>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 Director of Public Health.</p> <p>Individuals should have their immunisation status checked to ensure they are up to date with the recommended GHA 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 the 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 Director of Public Health. 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 GHA immunisation programmes.</p>
<p>Duration of treatment</p>	<p>See <u>dose and frequency of administration</u></p>
<p>Quantity to be supplied / administered</p>	<p>Single 0.5ml dose per administration.</p>

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<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 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).</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>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 Vaccine Incident Guidance.</p> <p>Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.</p>
<p>-----</p> <p>Disposal</p>	<p>-----</p> <p>-----</p> <p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator,</p>

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	<p>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.</p>
Drug interactions	<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>
Identification & 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 from the vaccine's SPC.</p>

Reporting procedure of adverse reactions	<p>Healthcare professionals and individuals and carers should 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 and send a copy of the Yellow card to the Director of Public Health</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>INFORM GIBRALTAR DIRECTOR OF PUBLIC HEALTH IMMEDIATELY IF SEVERE ADVERSE REACTION IS SUSPECTED</p>
Written information to be given to patient or carer	<p>Offer the 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>Also available in the GHA Public Health website.</p>
Patient advice / follow up treatment	<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 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 GHA 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 preschool and subsequent boosters should be given according to the GHA schedule.</p> <p>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.</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</p>
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	<p>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 familiarisethemselves 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>
Records	<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 Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016 • 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 • anatomical site of vaccination • advice given, including advice given if excluded or declines vaccination • details of any adverse drug reactions and actions taken • supplied via PGD <p>All records should be clear, legible and contemporaneous.</p> <p>This information should be recorded in the individual's GP record. Where the vaccine is administered outside the GP</p>

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	<p>setting, appropriate health records should be kept and the individual's GP informed.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes.</p>
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<p>4. Key references</p>	<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-infectiousdisease-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-withuncertain-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-andmanagement-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-healthcarewaste-hm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 https://www.gov.uk/government/publications/national-minimum-standards-andcore-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
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Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV):

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	<ul style="list-style-type: none"> • 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 <p>Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</p>
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5. Practitioner authorisation sheet

Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine

(Td/IPV): Revaxis®, suspension for injection in a pre-filled syringe PGD.

Date of issue: 11th April 2025 Date of review: 11th April 2027

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

Practitioner

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

Patient group directions 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.			
Name	Designation	Signature	Date

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Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the **GHA** for the above named health care 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.

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