**Patient Group Direction**
for *Pharmacists and Nurses to*
administer low dose diphtheria, tetanus and inactivated poliomyelitis vaccine (Td/IPV) Revaxis® for Travel in individuals aged Six years and over

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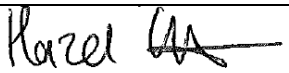
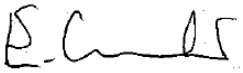
**It is the responsibility of the person using this PGD to ensure that they are using the most recent issue.**

| Developed by | Designation | Signature | Date |
|---|---|---|---|
| Athan Tachtatzis | PGD Pharmacist, NHS Fife |  | 11.02.22 |
| Lynne Campbell | Lead Nurse FVCV Immunisation Programme, NHS Fife |  | 22.02.22 |
| Hazel Close | Lead Pharmacist Public Health NHS Fife |  | 21.02.22 |

This Patient group Direction has been approved on behalf of NHS Fife by:

| Name | Designation | Signature | Date |
|---|---|---|---|
| Nicola Robertson | Associate Director of Nursing NHS Fife |  | 10.03.22 |
| Dr Esther Curnock | Deputy Director of Public Health Consultant in Public Health Medicine, NHS Fife |  | 16.03.22 |
| Fiona Forrest | Deputy Director of Pharmacy & Medicines NHS Fife |  | 11.03.22 |

## 1. Clinical condition to which the patient group direction applies

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| Indication | Active immunisation of individuals against tetanus, diphtheria or poliomyelitis. |
| Inclusion criteria | • Valid consent to treatment according to NHS Fife policy<br>Individuals aged 6 years and over who:<br>• intend to travel to or reside in countries where tetanus, diphtheria, or polio vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX www.travax.nhs.uk/destinations/<br>the risk of exposure should be determined after careful risk assessment of an individual's itinerary, duration of stay, planned activities and medical history.<br>• will be travelling to areas where proof of polio vaccination is required |
| Exclusion criteria | • No valid consent to treatment according to NHS Fife policy<br>Individuals who:<br>• are aged less than 6 years<br>• are pregnant (as pertussis containing vaccine maybe more appropriate)<br>• 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<br>• have had a confirmed anaphylactic reaction to any component of the vaccine, including formaldehyde, neomycin, streptomycin or polymyxin B (refer to relevant SPC)<br>• have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free.<br>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) |
| Cautions / Circumstances when further advice should be sought from a senior clinician | • It is the responsibility of the designated, authorised staff using this PGD to ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt, advice should be sought and recorded before the drug is administered / supplied.<br>• The Green Book advises that there are very few individuals who cannot receive low-dose diphtheria, tetanus and inactivated poliomyelitis vaccine (Td/IPV). Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the lead clinician.<br>• If under 10 years of age, ensure UK childhood immunisations are up to date as another tetanus/diphtheria/polio containing vaccine may be more appropriate. Vaccination status can be checked with paediatric immunisation team if required.<br>• 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 |

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| | 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.<br>• Individuals with immunosuppression can be given Td-IPV containing vaccines although these individuals may not make a full antibody response.<br>• 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. |
| Action if excluded | • Do not use the PGD<br>• The patient must be referred to an authorised prescriber<br>• The reason for referral should be documented<br><br>Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.<br><br>Document the reason for exclusion and any action taken in accordance with local procedures.<br><br>Inform or refer to the lead clinician in charge.<br><br>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.<br><br>Advise the individual/parent/carer of preventative measures to reduce exposure to polio through careful attention to food and water hygiene and hand washing.<br><br>Advise the individual/parent/carer of preventative measures to reduce exposure to diphtheria by practising good respiratory and hand hygiene, especially in overcrowded or busy places.<br><br>Advise the individual/parent/carer on wound cleansing and seeking medical help for tetanus prone injuries.<br><br>Individuals who have had a confirmed anaphylactic reaction to a previous dose of a Td-IPV containing vaccine or any components of the vaccines should be referred to a clinician for specialist advice and appropriate management. |
| Action if patient declines treatment | • The patient must be referred to an authorised prescriber<br>• The reason for refusal should be documented<br><br>• Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.<br><br>• Advise the individual/parent/carer of preventative measures to reduce exposure to polio through careful attention to food and water hygiene and |

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| | hand washing.<br>• Advise the individual/parent/carer of preventative measures to reduce exposure to diphtheria by practising good respiratory and hand hygiene, especially in overcrowded or busy places.<br>• Advise the individual/parent/carer on wound cleansing and seeking medical help for tetanus prone injuries.<br>• Document advice given and decision reached. Inform or refer to the lead clinician in charge. |

## 2. Medication details

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| Name strength & formulation of drug | Adsorbed diphtheria, tetanus, and inactivated poliomyelitis vaccine (Td/IPV): Revaxis® Suspension for injection in a pre-filled syringe. |
| Route of administration | Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm.<br>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<br>The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. |
| Dosage | 0.5ml |
| Frequency of administration | Single 0.5ml dose<br><br>Reinforcing doses:<br>Booster doses are required where immunisation was received more than 10 years ago.<br><br>*Polio:* Boosting may be required more frequently in those are travelling to areas where proof of polio vaccination is required |
| Duration of treatment including maximum/ minimum period if applicable | As above |
| Quantity to be supplied | Single 0.5ml dose per administration. |
| Patient advice verbal and written | Written information to be given to individuals:<br>• Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.<br><br>Individual advice / follow up treatment: |

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| | • Inform the individual/carer of possible side effects and their management.<br>• The individual should be advised to seek medical advice in the event of a severe adverse reaction.<br>• Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk.<br>• Advise the individual/parent/carer of preventative measures to reduce exposure to polio through careful attention to food and water hygiene and hand washing.<br>• Advise the individual/parent/carer of preventative measures to reduce exposure to diphtheria by practising good respiratory and hand hygiene, especially in overcrowded or busy places.<br>• Advise the individual/parent/carer on wound cleansing and seeking medical help for tetanus prone injuries. |
| Legal category | Prescription Only Medicine (POM) |
| Use outwith SPC | The 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 the HPS Guidance for Vaccine Storage and Handling must be followed (link). If a vaccine or cold chain incident occurs the Health Protection Scotland Vaccine Incident Guidance should be followed vaccine-incident-guidance-actions-to-take-in-response-to-vaccine-errors and advice must be sought from the Pharmacy Governance team by calling 01383 565347. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed. |
| Storage requirements | • Ensure within expiry date<br>• Vaccine should be stored at a temperature of +2° to +8°C.<br>• Store in the original packaging to protect from light.<br>• Do not freeze.<br>• Contact Pharmacy for advice if stored out with +2°C to +8°C<br>• There may be circumstances when vaccines stored out with the recommended storage temperatures of +2 to +8°C can be administered providing the product has been confirmed as suitable for use by the manufacturers and Pharmacy<br>• The HPS Guidance for Vaccine Storage and Handling must be followed (link) see above.<br>• 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. |
| Black Triangle Drug ▲ | No |
| Additional information | Minor illnesses without fever or systemic upset are not valid reasons to postpone |

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| | immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.<br><br>Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV): can be given at the same time as other vaccines.<br><br>When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. |
| Identification and management of adverse reactions | • For full details/information on possible side effects, refer to the marketing authorisation holder's SPC.<br><br>• 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.<br><br>• Common adverse reactions include pyrexia, headache, vertigo, nausea and vomiting.<br><br>• As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.<br><br>• In the event of severe adverse reaction individual should be advised to seek medical advice.<br><br>• Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.<br><br>• All suspected serious reactions should be reported directly to the MHRA/Commission on Human Medicines through the Yellow Card scheme and recorded in the patient's medical notes. Reports should be made online at https://yellowcard.mhra.gov.uk |
| Monitoring if required | Following immunisation, patients remain under observation in line with NHS Fife policy. |
| Follow up – appointment with or notification to GP required? | Not applicable |
| Additional facilities/ supplies required | • Immediate access to anaphylaxis medication as appropriate to current NHS Fife procedure for the Management of Anaphylaxis.<br>• Immediate telephone access to a senior clinician/authorised prescriber<br>• Access to a BNF<br>• NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) should be followed<br>• Adhere to hand decontamination policy |
| Disposal | As per SSUMPP |

## 3. Staff characteristics

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| Professional qualifications | The following classes of registered healthcare practitioners are permitted to administer vaccines:<br>• pharmacists currently registered with the General Pharmaceutical Council (GPhC)<br>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) |
| Specialist competencies or qualifications | Persons must only work under this PGD where they are competent to do so<br><br>All practitioners operating this PGD must demonstrate appropriate knowledge and skills to work under the PGD<br><br>All persons operating this PGD:<br>• must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it<br>• must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information<br>• must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent<br>• must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine<br>• must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions<br>• must have access to the PGD and associated online resources<br>• should fulfil any additional requirements defined by local policy<br>• have undertaken NHS Fife approved anaphylaxis management training<br>• have undertaken NHS Fife approved training in basic life support<br>• must be conversant with key issues in vaccine management (e.g. safe transport, maintaining cold-chain etc) in accordance with NHS Fife Policies<br>• It is essential that the NHS Fife approved PGD e-learning programme is accessed and completed by NHS Fife employed staff<br>• It is the responsibility of the designated authorised staff using this PGD to ensure that treatment with the vaccine detailed in the direction is appropriate. If in any doubt, advice should be sought and recorded before the vaccine is administered<br><br><u>Employer</u><br>The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD<br><br>• **As a minimum, competence requirements stipulated in the PGD must be adhered to** |
| Continued training requirements | • Maintain own professional level of competence and knowledge in this area<br><br>• Keep up-to-date with information on contraindications, cautions and interactions for Revaxis® from the BNF, SPC and PIL and refer to a senior clinician if necessary<br><br>• Annual update of anaphylaxis management according to NHS Fife Policy |

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| | • Annual update of training in paediatric and adult basic life support<br>• A 2 yearly update of the PGD e-learning programme is essential for NHS Fife employed staff. |

## 4. Referral arrangements/Audit trail

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| Arrangements for referral to medical advice | • The patient may be referred to a senior clinician at any stage, if this is necessary, in the professional opinion of the *healthcare professional*.<br>• |
| Records/Audit trail | • Enter in record<br>- date<br>- name of patient<br>- Date of birth/ CHI no.<br>- name of medicine<br>- batch number and manufacturer<br>- expiry date<br>- dose/volume<br>- quantity administered<br>- route and site of administration<br>- name of clinician providing treatment<br>- signature / individual log-on details of clinician providing treatment<br>• Record on appropriate form.<br>• Record medical history taken, diagnosis and the advice given to the patient/carer |
| References/ Resources & comments | • BNF / BNFc latest edition available at www.medicinescomplete.com<br>• NHS Fife Consent Policy<br>• NHS Fife Procedure for the Management of Anaphylaxis<br>• NHS Fife Resuscitation Guidelines<br>• NMC/RPS Administration of Medicines Guidance Jan 2019<br>• NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP)<br>• Summary of Product Characteristics available at www.medicines.org.uk<br>• Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book<br>• Immunisation Against Infectious Disease: The Green Book chapter 30 Chapter 15 and chapter 26<br>• Vaccination of individuals with uncertain or incomplete immunisation status. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status<br>• Current edition of British National Formulary.<br>• Marketing authorisation holder's Summary of Product Characteristics.<br>• All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s). |

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| | • Professional Guidance on the Administration of Medicines in Healthcare Settings 2019 https://www.rpharms.com/Portals/0/RPS document library/Open access/Professional standards/SSHM Admin/Admin Meds prof guidance.pdf/ver=2019-01-23-145026-567<br>• Professional Guidance on the Safe and Secure Handling of Medicines https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines<br>• PHE guidance on the vaccination of individuals with uncertain or incomplete immunisation status: https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status<br>• HPS Guidance for Vaccine Storage and Handling (link).<br>• HPS Vaccine Incident Guidance vaccine-incident-guidance-actions-to-take-in-response-to-vaccine-errors<br>• https://publichealthscotland.scot/publications/patient-group-direction-template-administration-of-low-dose-diphtheria-tetanus-and-inactivated-poliomyelitis-vaccine-tdipv/patient-group-direction-template-administration-of-low-dose-diphtheria-tetanus-and-inactivated-poliomyelitis-vaccine-tdipv/ |

**This Patient Group Direction has been assessed for Equality and Diversity Impact**

## 5. Management and monitoring of patient group direction

**Patient Group Direction**
for *Pharmacists and Nurses to*
administer **low dose diphtheria, tetanus and**
**inactivated poliomyelitis vaccine (Td/IPV) Revaxis® for Travel**
in individuals aged Six years and over

This patient group direction is to be read, agreed to, and signed by all *healthcare professionals* it applies to. One signed copy is to be given to each clinician with the original being kept on file by the line manager. One signed copy should be forwarded to the appropriate lead nurse / lead clinician where applicable.

**Pharmacist/Nurse Agreement**

I _____, confirm that I have read and understood the above Patient Group Direction. I confirm that I have the necessary professional registration, competence, and knowledge to apply the Patient Group Direction. I will ensure my competence is updated as necessary. I will have ready access to a copy of the Patient Group Direction in the clinical setting in which supply or administration of the medicine will take place.

I understand that it is the responsibility of the healthcare professional to act in accordance with the GPhC/ NMC Guidelines for Professional Practice and Guidelines for the Administration (or Supply) of Medicines and to keep an up to date record of training and competency.

Name of clinician----------

Professional Category----------

Registration No.----------

Is authorised to give **Revaxis**® under this patient group direction

Place of Work----------

Signature of clinician----------

Date----------

Authorised by: (not required for pharmacists)

Name of authorising clinician/manager----------

Signature----------

Date----------

**Pharmacists send signed copy of this page to fife.pgd@nhs.scot**

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