NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

# Patient Group Direction For The Administration Of Low Dose Diphtheria, Tetanus And Inactivated Poliomyelitis Vaccine (Td/IPV) (REVAXIS®) By Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

| | | |
|---|---|---|
| **Lead Author:**<br>Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG | **Consultation Group:**<br>See relevant page in the PGD | **Approver:**<br>NoS PGD Group<br><br>**Authorisation:**<br>NHS Grampian |

| | | |
|---|---|---|
| **Signature:** | | **Signature:** |

| | | |
|---|---|---|
| **NoS Identifier:**<br>NoS/PGD/Revaxis/ MGPG1216 | **Review Date:**<br>November 2023<br><br>**Expiry Date:**<br>November 2024 | **Date Approved:**<br>November 2021 |

**NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.**

**Uncontrolled when printed**

**Version 2.2 (Amended July 2022)**

## Revision History:

| | | |
|---|---|---|
| **Reference and approval date of PGD that has been adapted and/or superseded** | PGD adapted from PHS national PGD template and supersedes NoS/PGD/Revaxis/MGPG1216, v2.1.1 | |
| **Date of change** | **Summary of Changes** | **Section heading** |
| September 2021 | Yearly updated PGD adapted from PHS PGD template. This PGD has undergone minor rewording, layout, formatting changes. | |
| September 2021 | Statement regarding individuals who developed neurological complications following an earlier immunisation against diphtheria and/or tetanus removed in-line with updated Green Book recommendations and as per PHS PGD template. | Exclusion criteria |
| September 2021 | Statement regarding neurological conditions added as per updated Green Book and PHS PGD template. | Precautions and special warnings |
| September 2021 | Statement added regarding encephalopathy or encephalitis post immunisation as per PHS PGD template. | Precautions and special warnings |
| September 2021 | Off-label use updated as per PHS PGD template. | Legal status |
| September 2021 | Section updated as per PHS PGD template. | Frequency of dose/Duration of treatment |
| September 2021 | Uncommon and rare side effects removed. | Identifying and managing possible adverse reactions |
| September 2021 | Updated in-line with Green Book update. | Appendix 4 |
| November 2021 | Statement regarding Guillain-Barré syndrome, tetanus toxoids and phenylketonuria. | Precautions and Special warnings |
| March 2022 | Wording changed to include all healthcare professionals approved in current legislation that can operate under a PGD. | Professional qualifications and Authorisation of administration |
| March 2022 | Additional inclusion for a 10 year booster for exposure due to risk of occupational exposure added. | Inclusion criteria |

| | | |
|---|---|---|
| April 2022 | Minor amendment to Authorisation of Administration section due to omission of occupational therapist, orthoptist/prosthetists, radiographers and speech and language therapists to include all registered healthcare professionals that may be authorised to operate under this PGD. | Authorisation of administration |
| July 2022 | PGD transferred onto new NoS vaccine PGD template following an update to the PHS National PGD template. | Throughout |
| July 2022 | Inclusion criteria expanded to include other patient groups out with the Scottish childhood immunisation programme. | Inclusion criteria |
| July 2022 | Exclusion criteria updated to remove 'have completed a primary vaccine course or received a booster of a vaccine containing diphtheria or tetanus toxoid within the previous five years'. | Exclusion criteria |
| July 2022 | Section updated to include further information on the vaccination of tetanus cases and tetanus prone wounds in pregnancy and also vaccination in the response to an outbreak of diphtheria or polio. | Precautions and special warnings |
| July 2022 | Off-label administration to individuals who have received a vaccine containing diphtheria or tetanus toxoids within the previous five years when indicated for the management of primary immunisation and for cases and contacts of diphtheria or polio in accordance with disease management guidelines added. | Use out with SmPC |
| July 2022 | Additional information section added and then updated to include further information on tetanus and pertussis vaccination in pregnancy. | Additional Information |
| July 2022 | Specific NHST inclusion for addition of children requiring booster doses 6 months after completing chemotherapy. | Inclusion criteria |
| July 2022 | Previous supplementary appendices referring to management of individuals with tetanus-prone wounds and immunisation recommendations for tetanus-prone wounds removed. Links to Green Book added to ensure PGD remains up to date for this specific information. | Previously Appendix 3 and 4 |

**NoS Identifier:** NoS/PGD/Revaxis/MGPG1216 Version 2.2
**Keyword(s):** PGD Patient Group Direction low dose diphtheria tetanus inactivated poliomyelitis vaccine Td/IPV Revaxis immunisation tetanus prone wounds

**Policy Statement:**
It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

**Review date:** The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

| | | |
|---|---|---|
| Document: | Drafted: | September 2021 |
| | Completed: | November 2021 |
| | Approved: | November 2021 (Published – January 2022, August 2022) |
| | Amended and reauthorised: | March 2022, April 2022, July 2022 |

## Organisational Authorisations

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

**PGD Developed/Reviewed by;**

| | |
|---|---|
| **Medical practitioner** | **Name:** Dr Daniel Chandler<br>**Health Board:** NHST<br>**Title:** Consultant in Public Health Medicine<br>**Contact email:** daniel.chandler@nhs.scot<br>**Signature:** .....<br>**Date signed:** 25/07/2022 |
| **Senior representative of the professional group who will provide care under the direction** | **Name:** Lynda Davidson<br>**Health Board:** NHSH<br>**Title:** Health Protection Nurse Specialist<br>**Contact email:** lynda.davidson@nhs.scot<br>**Signature:** .....<br>**Date signed:** 17/08/2022 |
| **Lead author** | **Name:** Frances Adamson<br>**Health Board:** NHSG<br>**Title :** Medicines Management Specialist Nurse<br>**Contact email:** frances.adamson@nhs.scot<br>**Signature:** .....<br>**Date signed:** 19/07/2022. |
| **Pharmacist** | **Name:** Sharon Pfleger<br>**Health Board:** NHSH<br>**Title :** Consultant in Pharmaceutical Public Health<br>**Contact email:** sharon.pfleger@nhs.scot<br>**Signature:** .....<br>**Date signed:** 20/07/2022 |

## Approved for use within NoS Boards by;

| North of Scotland (NoS) PGD Group Chair | Signature | Date Signed |
|---|---|---|
| Lesley Coyle |  | 19/07/2022 |

## Authorised and executively signed for use within NoS Boards by;

| NHS Grampian Chief Executive | Signature | Date Signed |
|---|---|---|
| Professor Caroline Hiscox |  | 23/08/2022 |

## Management and Monitoring of Patient Group Direction

### PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

| Name: | Title: |
|---|---|
| Frances Adamson | **Lead Author:** Medicines Management Specialist Nurse NHSG |
| Sharon Pfleger | **Pharmacist:** Consultant in Pharmaceutical Public Health NHSH |
| Dr Daniel Chandler | **Medical Practitioner:** Consultant in Public Health Medicine NHST |
| Lynda Davidson | **Senior Representative:** Health Protection Nurse NHSH |
| Fiona Browning | Health Protection Nurse Specialist NHSG |
| Jackie Donachie | Vaccination Programme Manager NHST |
| Mary McFarlane | Principal Pharmacist NHSS |
| Russell Mackay | Specialist Clinical Pharmacist NHSO |
| Liam Callaghan | Chief Pharmacist NHSWI |
| Rhiannon Sharp | Occupational Health Nurse NHSG |

# Patient Group Direction For The Administration Of Low Dose Diphtheria, Tetanus And Inactivated Poliomyelitis Vaccine (Td/IPV) (REVAXIS®) By Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

## Clinical indication to which this PGD applies

| | |
|---|---|
| **Definition of situation/Condition** | This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer Td/IPV vaccine (REVAXIS®) as indicated for the active immunisation of individuals from 10 years of age for the prevention of diphtheria, tetanus and poliomyelitis, in accordance with the national immunisation programme and recommendations given in Chapter 15, Chapter 26 and Chapter 30 of Immunisation Against Infectious Disease: The Green Book.<br><br>This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book and the individual Summary of Product Characteristics (SmPC). |
| **Inclusion criteria** | Individuals aged 10 years and over who:<br><br>• 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).<br>• Have uncertain or incomplete immunisation status in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart.<br>• Have a tetanus-prone wound and tetanus immunisation is recommended in accordance with Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds or tetanus boosters are due soon and it is convenient to give now (see The Green Book Chapter 30).<br>• Require vaccination in line with recommendations for the management of cases and contacts of diphtheria or polio on the advice from individual Board Health Protection Team in accordance with Public health control and management of diphtheria (in England and Wales) guidelines or National polio guidelines: Local and regional services |

| | |
|---|---|
| | **The following inclusion is relevant to NHS Tayside only and does not apply in any other NoS Board -** Children requiring booster doses 6 months after completing chemotherapy.<br><br>**The following inclusion is relevant to NHS Grampian only and does not apply in any other NoS Board -** Healthcare workers who are at Occupational Risk of exposure requiring a 10 year booster.<br><br>For all Boards, prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy. |
| **Exclusion criteria** | Individuals who:<br><br>• Are aged less than 10 years<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 neomycin, streptomycin or polymyxin B<br>• Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free.<br>• Are suffering an acute severe febrile illness - immunisation should be postponed until fully recovered.<br><br>Individuals for whom no valid consent has been received. |
| **Precautions and special warnings** | Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.<br><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 relevant specialist, or from the local immunisation or health protection team.<br><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 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><br>If an individual 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.<br><br>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate.<br><br>If aged under 10 years assess for immunisation with DTaP/IPV/Hib/HepB, DTaP/IPV or dTaP/IPV as appropriate.<br><br>Td/IPV may be given to pregnant women when protection is required without delay, such as following a tetanus prone wound. However, pregnant women from week 16 of pregnancy onwards should instead be protected by the administration of the routinely indicated dTaP/IPV vaccine (see NoS dTaP/IPV PGD). |
| **Action if excluded from treatment** | Medical advice must be sought – refer to relevant medical practitioner for advice on the vaccine and circumstances under which it could be given using a patient specific direction.<br><br>The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records.<br><br>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged.<br><br>Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records. |

| | |
|---|---|
| **Action if treatment is declined** | Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached.<br><br>Inform/refer to the relevant medical practitioner if individual/parent/carer declines treatment.<br><br>Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records. |

## Description of vaccine available under the PGD

| | |
|---|---|
| **Name form and strength of vaccine** | Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV): REVAXIS® suspension for injection containing purified diphtheria toxoid, purified tetanus toxoid and three strains of inactivated polio virus. It is supplied as a 0.5mL pre-filled syringe. |
| **Legal status** | Td/IPV vaccine (REVAXIS®) is a Prescription-only Medicine (POM). |
| **Is the use out with the SmPC?** | Primary immunisation is off-label administration but in accordance with the recommendations given for individuals over 10 years of age in Chapter 15, Chapter 26 and Chapter 30 of The Green Book and national tetanus, diphtheria and polio disease management guidelines.<br><br>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 The Green Book.<br><br>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 Frequency of dose/Duration of treatment section).<br><br>The individual or the individual/parent/carer should be informed prior to the administration that the use is off-label, however the vaccine is being offered in accordance with national guidance. |

| | |
|---|---|
| | Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed. |
| **Dosage/Maximum total dose** | 0.5mL |
| **Frequency of dose/Duration of treatment** | **Routine Immunisation Schedule**<br>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 or (Boostrix®-IPV or Repevax®).<br><br>**UK immunisation schedule for previously unimmunised individuals or where there is an unknown or incomplete history of diphtheria, tetanus and poliomyelitis vaccination**<br>Those 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.<br><br>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.<br><br>A first booster dose should be administered at least 5 years after the third dose of the primary course.<br><br>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.<br><br>**Management of tetanus prone wounds**<br>Individuals requiring tetanus immunisation should be vaccinated in accordance with the recommendations in The Green Book Chapter 30 Table 30.1 and Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds. |

| | |
|---|---|
| | In accordance with those recommendations, individuals who are immunosuppressed may require additional boosting. Individuals may also require human tetanus immunoglobulin. **Note:** Administration of tetanus immunoglobulin is not covered by this PGD.<br><br>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.<br><br>**Management of cases and contacts of diphtheria**<br>Cases and contacts of diphtheria should be managed in accordance with Public health control and management of diphtheria guidelines and recommendations from the local health protection team.<br><br>Individuals who are fully immunised but have not received diphtheria containing vaccine in last 12 month may be given a single booster dose of diphtheria containing vaccine.<br><br>**Management of cases and contacts of polio**<br>Cases and contacts of polio should be managed in accordance with National polio guidelines: Local and regional services guidelines and recommendations from the local health protection team.<br><br>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. |
| **Maximum or minimum treatment period** | See Frequency of dose/Duration of treatment section. |
| **Route/Method of administration** | Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm.<br><br>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see The Green Book Chapter 4). |

| | |
|---|---|
| | The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration.<br>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.<br><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.<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 each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to Revaxis® vaccine. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records. |
| **Quantity to be administered** | 0.5mL per administration. |
| **Storage requirements** | Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily.<br><br>Store in original packaging in order to protect from light.<br><br>Do not freeze.<br><br>Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.<br><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. |
| **Additional Information** | Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV): can be given at the same time as other vaccines. |
| **Follow-up (if applicable)** | Following immunisation patients should remain under observation in line with individual NHS Board policy. |

| | |
|---|---|
| | Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice. |
| **Advice (Verbal)** | • Advise individual/parent/carer what to expect and of the 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>• Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.<br><br>When administration is postponed advise the individual/parent/carer when to return for vaccination.<br><br>If appropriate, advise when subsequent doses are due and if any follow up is required. |
| **Advice (Written)** | The PIL contained in the medicine(s) should be made available to the individual/parent/carer. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.<br><br>Supply immunisation promotional material as appropriate.<br><br>More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation |
| **Identifying and managing possible adverse reactions** | 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.<br><br>The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. 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. |

| | |
|---|---|
| | **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.**<br><br>**BNF/BNFC**:<br>BNF British National Formulary - NICE<br>BNF for Children British National Formulary - NICE<br><br>**SmPC/PIL/Risk Minimisation Material:**<br>Home - electronic medicines compendium (emc)<br>MHRA Products \| Home<br>RMM Directory - (emc)<br><br>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record.<br><br>Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA |
| **Facilities and supplies required** | The following are to be available at sites where the vaccine is to be administered:<br>• Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit)<br>• An acceptable level of privacy to respect individual's right to confidentiality and safety<br>• Basic airway resuscitation equipment (e.g. bag valve mask)<br>• Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection<br>• Access to a working telephone<br>• Another competent adult, who can summon urgent emergency support if required should ideally be present<br>• Access to medical support (this may be via the telephone)<br>• Approved equipment for the disposal of used materials<br>• Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel<br>• A copy of this PGD in print or electronically |

## Characteristics of staff authorised to administer vaccine under PGD

| | |
|---|---|
| **Professional qualifications** | The following classes of registered healthcare practitioners are permitted to administer vaccines as identified and included in individual Board immunisation delivery plans: |

| | |
|---|---|
| | • Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)<br>• Pharmacists currently registered with the General Pharmaceutical Council (GPhC)<br>• Chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)<br>• Dental hygienists and dental therapists registered with the General Dental Council<br>• Optometrists registered with the General Optical Council. |
| **Specialist competencies** | **Approved by the organisation as:**<br>• Competent to assess the individual's/parent's/carer's capacity to understand the nature and purpose of vaccination in order to give or refuse consent<br>• Familiar with the vaccine product and alert to changes in the product information.<br>• Competent to undertake administration of the vaccine and discuss issues related to vaccination<br>• Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions<br>• Competent in the handling and storage of vaccines, and management of the "cold chain"<br>• Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD. |
| **Ongoing training and competency** | **All professionals working under this PGD must:**<br>• Have undertaken NoS PGD module training on TURAS Learn<br>• Have attended basic life support training either face to face or online and updated in-line with individual Board requirements<br>• Have undertaken immunisation training<br>• Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements<br>• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the vaccine. |

| | |
|---|---|
| | If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD.<br>• Have knowledge and familiarity of the following;<br>○ Current edition of the Green Book<br>○ SmPC for the vaccine to be administered in accordance with this PGD<br>○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board<br>○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s). |
| **Responsibilities of professional manager(s)** | **Professional manager(s) will be responsible for;**<br><br>Ensuring that the current PGD is available to all staff providing care under this direction.<br><br>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.<br><br>Maintain up to date record of all staff authorised to administer the vaccine specified in this direction. |

## Documentation

| | |
|---|---|
| **Authorisation of administration** | Qualified registered healthcare professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following:<br><br>Nurses, midwives and health visitors can be authorised by their line manager.<br><br>Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration.<br><br>The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. |

| | |
|---|---|
| | All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board. |
| **Record of administration** | An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:<br>• Date and time of vaccine administration<br>• Individuals name, address and CHI<br>• GP with whom the individual is registered<br>• Exclusion criteria, record why the vaccine was not administered (if applicable)<br>• Record that valid consent to treatment under this PGD was obtained<br>• The name, brand, dose, form, batch number, expiry date, route/and anatomical site of the vaccination administered<br>• Advice given, including advice given if excluded or declined vaccination under this PGD<br>• Signature and name in capital letters of the healthcare professional who administered the vaccine, and who undertook the assessment of the individual's clinical suitability for the vaccine<br>• Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner).<br><br>Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate.<br>• Individual's GP records if appropriate<br>• Individual service specific systems.<br><br>Local policy should be followed with respect to sharing information with the individual's General Practitioner.<br><br>All records should be clear, legible and contemporaneous and in an easily retrievable format. |
| **Audit** | All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD. |

| | |
|---|---|
| **References** | Electronic Medicines Compendium http://www.medicines.org.uk REVAXIS® - Date of revision of text 24/07/20, accessed 19/07/2022.<br><br>British National Formulary for Children and the British National Formulary accessed 19/07/2022.<br><br>Department of Health (2006): Immunisation against Infectious Disease [Green Book]<br><br>Diphtheria: the green book, chapter 15 - GOV.UK (www.gov.uk)<br><br>Polio: the green book, chapter 26 - GOV.UK (www.gov.uk)<br><br>Tetanus: the green book, chapter 30 - GOV.UK (www.gov.uk)<br>American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33. |

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

**Appendix 1**

## Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

**I:** _____ (Insert name)

**Working within:** _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

## Patient Group Direction For The Administration Of Low Dose Diphtheria, Tetanus And Inactivated Poliomyelitis Vaccine (Td/IPV) (REVAXIS®) By Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

**Signed:** _____

**Print Name:** _____

**Date:** _____

**Profession:** _____

**Professional Registration number/PIN** _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

**Appendix 2**

## Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

| |
|---|
| **The Lead manager/Professional** of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated. |
| **The Senior Nurse/Professional** who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons. |
| **The Healthcare Professional** that is approved to administer the vaccine under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct. |
| **Patient Group Direction For The Administration Of Low Dose Diphtheria, Tetanus And Inactivated Poliomyelitis Vaccine (Td/IPV) (REVAXIS®) By Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles** |
| **Local clinical area(s) where the listed healthcare professionals will operate under this PGD:** |

| Name of Healthcare Professional | Signature | Date | Name of Manager | Signature | Date |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

| Patient Group Direction For The Administration Of Low Dose Diphtheria, Tetanus And Inactivated Poliomyelitis Vaccine (Td/IPV) (REVAXIS®) By Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles | | | | | |
|---|---|---|---|---|---|
| **Name of Healthcare Professional** | **Signature** | **Date** | **Name of Manager** | **Signature** | **Date** |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |