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 Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from Public Health Scotland Administration Of Low-Dose Diphtheria, Tetanus And Inactivated Poliomyelitis Vaccine (Td/IPV) Patient Group Direction (PGD) template, Version 2.1 – PHS Publication date 1st March 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Revaxis/1563	**Review Date:** 28th February 2026 **Expiry Date:** 28th February 2026	**Date Approved by NoS:** 18th November 2024

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 2.1

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/Revaxis/MGPG1216, Version 2.2 (NoS Version)

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
2.1	24th April 2024	Reference to NoS Appendix 1 and 2.	Authorisation
		Training requirements for NoS.	Continuing education and training

PHS recent changes

Version	Date	Summary of changes
2.1	1st March 2024	The following changes to version 2.0 of the PGD have been made: • Minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs. • Inclusion criteria, frequency, is the use outwith the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of individuals following haematopoietic stem cell transplant or CAR-T treatment. • Observation following vaccination section updated to include advice on driving post-immunisation.

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.

Contents Page

Authorisation

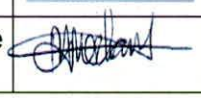
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

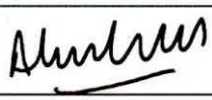
A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Susan Laidlaw	Signature		Date Signed	13/11/2024
Pharmacist	Fiona Marion	Signature		Date Signed	14/11/2024
Nurse	Pauline Merchant	Signature		Date Signed	14/11/2024

Approved for use within NoS by:

NoS Group Chair	Signature	Date Signed
Lesley Coyle		15/11/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		18/11/2024

Version 2.1– Approved for NoS from 18th November 2024

1. Clinical Situation

1.1. Indication

Immunisation of individuals from 10 years of age, against diphtheria, tetanus and poliomyelitis.

1.2. Inclusion criteria

Individuals aged 10 years and over who:

- require a booster following a primary course of immunisation against diphtheria, tetanus and poliomyelitis (this booster is usually offered at 13 to 18 years of age, unless the course has already been completed).
- have uncertain or incomplete immunisation status in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart.
- 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).
- 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.
- Individuals who have received a haematopoietic stem cell transplant or CAR-T therapy and who require revaccination, in accordance with the Scottish Haematology Society Revaccination Schedule.

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- are aged less than 10 years.
- 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.
- have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free.
- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

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.

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.

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.

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.

If aged under 10 years assess for immunisation with DTaP/IPV/Hib/HepB, DTaP/IPV or dTaP/IPV as appropriate.

Co-administration with other vaccines

Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV) can be given at the same time as other vaccines.

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.

Syncope

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.

Pregnancy and breastfeeding

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 separate PGD).

1.5. Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

1.6. Action if patient declines

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.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description Of Treatment

2.1. Name of medicine/form/strength

Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV): Revaxis®. Suspension for injection in a pre-filled syringe.

2.2. Route of administration

Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm.

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 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.

The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration.

The vaccine's normal appearance is a cloudy white suspension that may sediment during storage. Shake the pre-filled syringe well to distribute uniformly the suspension before administering the vaccine.

The vaccine should be visually inspected for 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.

2.3. Dosage

0.5mL.

2.4. Frequency

Routine Immunisation Schedule

Td/IPV is routinely offered to teenagers as a second booster dose at around 14 years of age. It should ideally be given 10 years after the first booster dose. It should be given at the school session or scheduled appointment provided a minimum of 5 years have elapsed between the first and second boosters. (**Note:** the first booster is usually given at pre-school age using dTaP/IPV (Boostrix®-IPV or Repevax®).

UK immunisation schedule for previously unimmunised individuals or where there is an unknown or incomplete history of diphtheria, tetanus and poliomyelitis vaccination

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.

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.

A first booster dose should be administered at least 5 years after the third dose of the primary course.

A second booster dose should be administered a minimum of 5 years, ideally 10 years, after the first booster dose, if less than 5 doses of diphtheria, tetanus and polio vaccine are documented.

Management of tetanus-prone wounds

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. Administration of tetanus immunoglobulin is not covered by this PGD.

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.

Management of cases and contacts of diphtheria

Cases and contacts of diphtheria should be managed in accordance with Public health control and management of diphtheria guidelines and recommendations from the local health protection team.

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.

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 guidelines and recommendations from the local health protection team.

Management will depend on the level of exposure but may include the administration of a single dose of IPV containing vaccine, regardless of vaccine history.

Revaccination of individuals who have received a haemopoietic stem cell transplant

In accordance with the schedule recommended by the Scottish Haematology Society Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment.

2.5. Duration of treatment

See frequency section.

2.6. Maximum or minimum treatment period

See frequency section.

2.7. Quantity to supply/administer

See frequency section.

2.8. ▼ black triangle medicines

No.

2.9. Legal category

Prescription only medicine (POM).

2.10. 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 Green Book Chapter 15, Chapter 26 and Chapter 30 and national tetanus, diphtheria and polio disease management guidelines.

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 Green Book Chapter 15 and Chapter 30.

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 section).

Revaccination of individuals following haematopoietic stem cell transplant of CAR-T treatment is considered off-label but is in accordance with the Scottish Haematology Society schedule.

Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to National Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.

2.11. Storage requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Store in the original packaging to protect from light.

Do not freeze.

NHS Board guidance on Storage and Handling of vaccines should be observed.

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.

2.12. Additional information

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.

3. Adverse Reactions

3.1. Warnings including possible adverse reactions and management of these

Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the injection site.

Common adverse reactions include pyrexia, headache, vertigo, nausea and vomiting.

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of severe adverse reaction individual should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://www.mhra.gov.uk/yellowcard

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.

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Supply immunisation promotional material as appropriate.

Individual advice / follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://www.mhra.gov.uk/yellowcard

3.4. Observation following vaccination

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

Following immunisation, patients remain under observation in line with NHS board policy.

3.5. Follow up

Not applicable.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics Of Staff Authorised Under The PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists currently registered with the General Pharmaceutical Council (GPhC)
- 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)
- dental hygienists and dental therapists registered with the General Dental Council
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/summary of product information.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

Employer

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.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

- Have undertaken NoS PGD module training on TURAS Learn
- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements

- Have undertaken immunisation training where available
- 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
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

5. Audit Trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional References

- Immunisation against Infectious Disease [Green Book]
- Immunisation Against Infectious Disease: The Green Book chapter 15, chapter 26 and chapter 30.
- Vaccination of individuals with uncertain or incomplete immunisation status.
- National polio guidelines PHE.
- Public health control and management of diphtheria in England.
- Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus prone wounds England.
- Current edition of British National Formulary.
- Marketing authorisation holder's Summary of Product Characteristics.
- All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).

- Professional Guidance on the Administration of Medicines in Healthcare Settings 2019.
- Professional Guidance on the Safe and Secure Handling of Medicines.
- Scottish Haematology Society advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment

7. Version History

Version	Date	Summary of changes
1.0	1 Sept 2021	Version 1.0 new PGD
2.0	1 June 2022	• Inclusion criteria expanded to include other patient groups out with the Scottish childhood immunisation programme. • 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.' • Frequency section updated to include dosing information for the other patient groups out with the Scottish childhood immunisation programme. • Caution/further advice 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. • Use out with SmPC section updated to include 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.
2.1	1 March 2024	The following changes to version 2.0 of the PGD have been made: • minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs • Inclusion criteria, frequency, is the use outwith the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of individuals following haematopoietic stem cell transplant or CAR-T treatment. • Observation following vaccination section updated to include advice on driving post-immunisation

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

Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) 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 Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) 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 Medicine(s) 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 medicine(s) 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 medicine(s) 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 Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1
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

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**