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

Patient Group Direction for the Administration of diphtheria, tetanus, acellular pertussis with or without inactivated poliomyelitis vaccine by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Adapted from Public Health Scotland Administration of diphtheria, tetanus, acellular pertussis with or without inactivated poliomyelitis vaccine Patient group direction (PGD) template Version 1.1 – PHS Publication date 21st June 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Dtap_IPV _Pertussis/1520	**Review Date:** 28th of February 2026 **Expiry Date:** 28th of February 2026	**Date Approved by NoS:** 27th June 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 1.1 (Amended June 2024)

Revision History for NoS:

NoS PGD that has been superseded	PGD adapted from PHS national PGD and PGD supersedes NoS/PGD/dTaP_IPV/MGPG1161, Version 1.5

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
1.1	25 June 2024	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
1.1	27 July 2024	Tayside Inclusions removed	Inclusion Criteria

PHS recent changes

Version	Date	Summary of changes
1.1	21 June 2024	Updated link to pertussis guidance.

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

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	Louise Wilson	Signature		Date Signed	26/06/2024
Pharmacist	Kirsten Smith	Signature		Date Signed	27/06/2024
Nurse	Jacqueline Donachie	Signature		Date Signed	26/06/2024

Approved for use within NoS by:

NoS Group Chair	**Signature**	**Date Signed**
David Pfleger – Director of Pharmacy NHSG on behalf of Lesley Coyle		27/06/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Adam Coldwells – Interim Chief Executive		27/06/2024

Version 1.1 – Approved for NoS from 27th June 2024

1. Clinical situation

1.1. Indication

Immunisation of individuals against diphtheria, tetanus and pertussis or immunisation of individuals against diphtheria, tetanus, pertussis and poliomyelitis.

1.2. Inclusion criteria

- Individuals from 3 years to under 10 years of age who require a booster following a primary course of immunisation against diphtheria, tetanus, pertussis and poliomyelitis.
- Pregnant women from week 16 of pregnancy (ideally between weeks 16 and 32, see pregnancy and breastfeeding section).
- Mothers with an infant less than 2 months of age who did not receive pertussis vaccination during their pregnancy.
- 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.
- Healthcare workers who have not received a pertussis containing vaccine in the last five years and have regular contact with pregnant women or young infants in accordance with Scottish Government policy

Individuals from 3 years of age (see cautions/need for further advice section) who:

- have uncertain or incomplete primary vaccine history (vaccinate 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 NHS 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.
- require vaccination in line with recommendations for the management of cases and contacts of pertussis on the advice from individual NHS Board Health Protection Team in accordance with Guidelines for the Public Health Management of Pertussis.
- Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis 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 or residual products from manufacture, these may include formaldehyde, glutaraldehyde, streptomycin, neomycin, polymyxin and bovine serum albumin.
- have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free. ADACEL® contains latex in the tip cap.
- are less than 16 weeks pregnant (with the exception of post exposure vaccination, at any stage of pregnancy, of contacts at risk of transmitting pertussis to vulnerable individuals).
- are pregnant and have already received a dose of pertussis-containing vaccine from 16 weeks in this pregnancy.
- other than in pregnant women receiving pertussis-containing vaccine from 16 weeks of pregnancy, who have not yet completed **primary** immunisation with three doses of diphtheria, tetanus, pertussis and poliomyelitis antigen unless recommended by a local health protection team.
- have received a dose of a diphtheria, tetanus, pertussis or poliomyelitis-containing vaccines within the last 4 weeks.
- experienced transient thrombocytopenia, and/or neurological complications following a previous dose of diphtheria and or tetanus-containing vaccine.
- 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 diphtheria, tetanus, acellular pertussis with and without inactivated poliomyelitis vaccine (Boostrix-IPV, Repevax or ADACEL®). 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.

If a seizure associated with a fever occurred within 72 hours of a previous immunisation with pertussis-containing vaccine, immunisation should continue as recommended if a cause was identified, or the child recovered within 24 hours. However, if no underlying cause was found and the child did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable.

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.

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.

Individuals who are immunosuppressed may not be adequately protected against tetanus, despite having been fully immunised. In the event of an exposure they may require additional boosting and/or immunoglobulin (see the Green Book Chapter 30 and Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds).

Individuals over 10 years of age should preferably be vaccinated using Td/IPV (Revaxis®) where protection against pertussis is not required. However, Boostrix-IPV or Repevax may be offered to individuals with a tetanus-prone wound and cases or contacts of diphtheria or polio where Td/IPV (Revaxis®) is either not available or Boostrix-IPV or Repevax is recommended by the local health protection team.

Repevax and Boostrix-IPV) vaccine contains a lower dose of pertussis antigen, as well as a lower dose of diphtheria antigen, compared to DTaP/IPV (Infanrix®-IPV) or DTaP/IPV/Hib/HepB. It is important that **primary** vaccination in children under 10 years of age is undertaken using a product with higher doses of pertussis, diphtheria and tetanus antigens (currently that is DTaP/IPV/Hib/HepB) to ensure that adequate priming occurs.

Therefore, individuals immunised as part of an outbreak response but who have not completed primary immunisation should be immunised in accordance with Vaccination of individuals with uncertain or incomplete immunisation status algorithm. Appropriate advice should be sought from the local immunisation or health protection team.

Co-administration with other vaccines

Diphtheria, tetanus, pertussis (acellular component) with and without poliomyelitis vaccine 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

Except for individuals with a documented history of severe allergy to latex, ADACEL® is the preferred vaccine to offer in the maternal pertussis programme, in line with JCVI advice to offer a non IPV-containing pertussis vaccine. If ADACEL® is not locally available to offer at the time of the vaccination, Boostrix-IPV or Repevax vaccine is permitted under this PGD.

Vaccination to protect against pertussis should be offered to pregnant women between weeks 16 and 32 to maximise the likelihood that the baby will be protected from birth.

Women may still be vaccinated after week 32 of pregnancy but this may not offer as high a level of passive protection against pertussis to the baby.

Women pregnant with twins or multiple pregnancies require a single dose of diphtheria, tetanus, pertussis with or without poliomyelitis vaccine.

Women who become pregnant again should be offered immunisation during each pregnancy.

Pertussis vaccination is recommended after the fetal anomaly scan to prevent any identified anomalies being inappropriately attributed to vaccination. The fetal anomaly scan usually takes places between 18^{+0} and 20^{+6} weeks gestation. Mothers declining the anomaly scan should continue to be offered pertussis vaccination.

If a person has received vaccination for a tetanus-prone wound from week 16 of this pregnancy with a vaccine also containing pertussis antigen then the additional dose in pregnancy would not be required, refer to advice in Green Book Chapter 30.

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 the case of women who have received immunisation against pertussis, tetanus, diphtheria and/or poliomyelitis within the preceding four weeks, the immunisation should be rearranged to ensure there is a gap of at least four weeks between doses.

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

Diphtheria, tetanus, pertussis (acellular component) and poliomyelitis (inactivated) vaccine (adsorbed):

Boostrix®-IPV, suspension for injection in pre-filled syringe (reduced antigen content).

Repevax®, suspension for injection in pre-filled syringe (reduced antigen content).
Low dose diphtheria, tetanus and pertussis (acellular component) vaccine (adsorbed):

ADACEL® suspension for injection in pre-filed syringe (reduced antigen content),
In pregnant women from week 16 of pregnancy, ADACEL® is the preferred vaccine for the pregnancy programme. Where ADACEL® is not clinically suitable or where ADACEL® is unavailable, administration of Boostrix-IPV® or Repevax® is authorised under this PGD.

2.2. Route of administration

Administer by intramuscular injection.

The preferred site is the deltoid region of the upper arm.

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 administered with reasonable safety by this route. 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 treatment is administered. 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. 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 or carer should be informed about the risk of haematoma from the injection.

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's normal appearance is a uniform cloudy, white suspension which may sediment during storage. Shake the prefilled syringe well to uniformly distribute 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 Childhood Immunisation Schedule

The Boostrix-IPV or Repevax booster should ideally be given three years after completion of the primary course of diphtheria, tetanus, pertussis and polio vaccination as the first booster dose and is recommended as a pre-school vaccine at around 3 years and 4 months of age though it may be used until 10 years of age.

When primary vaccination has been delayed, this first booster dose may be given provided it is at least 12 months since the last primary dose was administered.

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. Additional doses of DTaP-containing vaccines given under 3 years of age do not count as a booster to the primary course in the UK. The routine pre-school and subsequent boosters should be given according to the UK schedule.

Individuals with uncertain or incomplete primary vaccine history should be vaccinated in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart.

In pregnant and newly delivered women

Single dose.

Revaccination of individuals who have received a haematopoietic 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.

Healthcare workers who have not received a pertussis containing vaccine in the last five years and have regular contact with pregnant women or young infants

Single dose.

Management of tetanus-prone wounds

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 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.**

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 (in England and Wales) guidelines and recommendations from the local health protection team.

Individuals who are fully immunised but have not received diphtheria containing vaccine in the last 12 months 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.

Management of cases and contacts of pertussis

A single dose of Boostrix-IPV or Repevax should be administered to contacts recommended immunisation in accordance with Guidelines for the Public Health Management of Pertussis who have not received a dose of pertussis-containing vaccine in the last five years, are not otherwise eligible for ADACEL® and have not received Td/IPV vaccine in the preceding 4 weeks.

A pertussis-containing vaccine is recommended at any stage of pregnancy for pertussis contacts in Group 2 (b, c or d)[1], at increased risk of transmitting to vulnerable individuals in Group 1[2], who have not received a pertussis-containing vaccine in the last five years, and who happen to be pregnant as well.

Where such vaccination of pregnant contacts occurs before 16 weeks of pregnancy, a further dose of pertussis-containing vaccine will be required after 16 weeks of pregnancy in accordance with the routine immunisation schedule and at least 4 weeks after the preceding dose.

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 outwith the SmPC?

Yes.

[1]Group 2: b) healthcare workers working with infants and pregnant women c) people whose work involves regular, close or prolonged contact with infants too young to be fully vaccinated d) people who share a household with an infant too young to be fully vaccinated

[2]Group 1: Individuals at increased risk of severe complications ('vulnerable'): • unimmunised infants (born after 32 weeks) less than 2 months of age whose mothers did not receive pertussis vaccine after 16 weeks of pregnancy and at least 2 weeks prior to delivery • unimmunised infants (born < 32 weeks) less than 2 months of age regardless of maternal vaccine status • unimmunised and partially immunised infants (less than 3 doses of vaccine) aged 2 months and above regardless of maternal vaccine status.

Administration of Boostrix®-IPV by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration but may be considered where this remains in line with advice in Green Book Chapter 4. Firm pressure should be applied to the injection site (without rubbing) for at least two minutes in accordance with the recommendations in the product's SmPC. **Note:** The Repevax® SmPC includes consideration of administration by deep subcutaneous injection to individuals with bleeding disorders.

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.

ADACEL®, Boostrix® and Repevax® SPCs all advise vaccination is contraindicated for individuals who developed encephalopathy within 7 days of receiving a vaccine containing pertussis antigen. In line with advice outlined in Chapter 30: neurological conditions (update to Chapter 24 pending), deferral of vaccination should be considered where there is evidence of current neurological deterioration of the condition, to avoid incorrect attribution of any change, whilst balancing the risk of deferral against the risk of preventable infection. Vaccination should be given promptly once the diagnosis is clear, the expected course of the condition is known, or both.

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

3.2. 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. Headache and fatigue are also very commonly reported.

Nausea, arthralgia and myalgia are very commonly reported side effects of Repevax.

Generalised aching or muscle weakness and diarrhoea are very commonly reported side effects specific to ADACEL®.

Common adverse reactions include fever and gastrointestinal disturbances (diarrhoea and vomiting). Injection-site haematoma, pruritus, warmth and numbness have also been commonly reported with Boostrix-IPV. 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.

3.3. Reporting procedure for adverse reactions

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

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.

3.4. 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

3.5. 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.

3.6. Follow up

Not applicable.

3.7. 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

Practitioners operating the PGD must be familiar with:

- Immunisation against Infectious Disease [Green Book].
- Immunisation Against Infectious Disease: The Green Book chapter 15, chapter 24, chapter 26 and chapter 30.
- Vaccination of individuals with uncertain or incomplete immunisation status.
- Scottish Haematology Society advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment
- Guidelines for the Public Health Management of Pertussis .
- 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

7. PHS Version history

Version	Date	Summary of changes
1.0	19 June 2024	New PGD based on previous dTaP/IPV PGD v 4.1 following introduction of ADACEL® for use in pregnancy.
1.1	21 June 2024	Updated link to pertussis guidance.

NoS Version History

1.0 (Unpublished)	19 June 2024	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
1.0 (Unpublished)	19 June 2024	Children requiring booster post chemotherapy (NHST only) added.	Inclusion criteria
1.0 (Unpublished)	19 June 2024	Further information added in regard to NHST only inclusion for post chemotherapy boosters.	Frequency
1.1	25 June 2024	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
1.1	27 July 2024	Tayside Incisions removed	Inclusion Criteria

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 diphtheria, tetanus, acellular pertussis with or without inactivated poliomyelitis vaccine by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 1.1

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 diphtheria, tetanus, acellular pertussis with or without inactivated poliomyelitis vaccine by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 1.1
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

Patient Group Direction for the Administration of diphtheria, tetanus, acellular pertussis with or without inactivated poliomyelitis vaccine by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 1.1					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**