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

Patient Group Direction For The Administration of Diphtheria, Tetanus, Pertussis And Poliomyelitis Vaccine (dTaP/IPV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/dTaP/IPV/MGPG 1161	**Review Date:** May 2023 **Expiry Date:** May 2024	**Date Approved:** May 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 1.3 (Amended July 2022)

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD adapted from PHS national PGD and PGD supersedes NoS/PGD/dTaP_IPV/MGPG1161, Version 1.2

Date of change	**Summary of Changes**	**Section heading**
February 2021	One dTaP/IPV PGD created by amalgamating previous NoS Boostrix®-IPV and Repevax® PGDs.	
February 2021	Indication added to prevent secondary cases of pertussis following an outbreak.	Inclusion criteria
February 2021	Indication added for the management of cases and contacts of diphtheria or polio.	Inclusion criteria
February 2021	Removal of latex allergy from exclusions as Boostrix®-IPV has a stopper made from butyl rubber which is a synthetic latex made from petroleum, and does not contain the naturally occurring proteins found in natural rubber latex.	Exclusion criteria
May 2021	Additional information regarding Boostrix®-IPV administration off-label added.	Legal Status
October 2021	Age changed from 3 years 4 months to 3 years as per national PHS PGD.	Inclusion criteria and Exclusion criteria
October 2021	Encephalopathy or encephalitis removed from exclusion criteria as per national PHS PGD.	Exclusion criteria
October 2021	Statement regarding encephalopathy or encephalitis added as per national PHS PGD.	Precautions and special warnings
October 2021	Exclusion for transient thrombocytopenia, neurological complications following a previous dose of diphtheria and or tetanus containing vaccine removed as per Green Book and national PHS PGD.	Exclusion criteria
October 2021	Currently suffering from a neurological condition that has not been investigated and stabilised removed from section as per PHS PGD.	Exclusion criteria
October 2021	Statement regarding current neurological condition added as per national PHS PGD.	Precautions and special warnings
October 2021	Childhood immunisation details updated as per PHS PGD.	Frequency of dose/Duration of treatment

October 2021	Information regarding the subcutaneous administration of Boostrix®-IPV corrected as its Repevax® SmPC that states it shouldn't be administered via this route, and not Boostrix®-IPV.	Legal status
October 2021	Statement of administration to individuals who have experienced an encephalopathy of unknown origin within 7 days of previous vaccination with a pertussis-containing vaccine being off-label added as per national PHS PGD.	Legal status
February 2022	Change to sentence to include the term 'woman with infants less than 2 months old'.	Inclusion criteria
February 2022	Additional exclusions added for those who have had a previous dose of dTap/IPV in the previous month, and for those who have had transient thrombocytopenia and neurological conditions following a previous dose.	Exclusion criteria
February 2022	Removal of statement regarding off-label use of repevax in bleeding disorders as SmPC allows for this in exceptional circumstances.	Legal status
February 2022	Addition of statement from PHS PGD in regard to using vaccines that have been stored out with usual conditions.	Legal status
February 2022	Section updated with statement from PHS PGD regarding inadvertent or unavoidable deviation of storage conditions.	Storage requirements
February 2022	Specific staff groups of nurses and midwives removed and replaced with generic statement allowing all healthcare professionals as authorised in the legislation to work under the PGD.	Professional qualifications
February 2022	Updated to include authorisation details for all healthcare professionals who are authorised in the legislation to work under a 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	NHS Tayside specific inclusion added to PGD.	Inclusion criteria
July 2022	Section updated to include further information on the vaccination of tetanus cases and tetanus prone wounds and also vaccination in the response to an outbreak of diphtheria, polio or pertussis.	Precautions and special warnings
July 2022	Additional information section added and then updated to include further information on tetanus and pertussis vaccination in pregnancy.	Additional Information

NoS Identifier:	NoS/PGD/dTaP/IPV/MGPG1161 Version 1.3
Keyword(s):	PGD Patient Group Direction vaccine diphtheria tetanus pertussis poliomyelitis pregnancy Boostrix®-IPV Repevax® healthcare workers OHS immunisation

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:	February 2021
	Completed:	March 2021
	Approved:	May 2021 (published May 2021, October 2021, February 2022 and September 2022
	Amended and reauthorised:	October 2021, February 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 Maggie Watts **Health Board:** NHSWI **Title:** Director of Public Health **Contact email:** Maggie.watts@nhs.scot **Signature** ..... **Date:**
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Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		16/08/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		26/08/2022

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
Liam Callaghan	**Pharmacist:** Chief Pharmacist NHSWI
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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 combined Diphtheria, Tetanus, Pertussis and Poliomyelitis Vaccine (dTaP/IPV) for the immunisation of healthcare workers, pregnant and newly delivered women against pertussis (whooping cough) in line with the current Scottish Government CMO Direction, and to children from 3 years to under 10 years of age in-line with the Scottish Government Health Directorate Childhood Immunisation Programme. This PGD also allows for the administration of a **booster dose** of combined Diphtheria, Tetanus, Pertussis and Poliomyelitis Vaccine (dTaP/IPV) to healthcare workers and children aged 3 years to under 10 years of age identified as requiring a booster dose, or in the management of an outbreak or as an identified close contact. 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 Chapter 15, 30, 24 and 26 and the individual Summary of Product Characteristics (SmPC).
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 additional information section) • Mothers with an infant less than 2 months of age who did not receive pertussis vaccination during their pregnancy. • Revaccination of individuals who have received a haemopoietic stem cell transplant

	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 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 Board Health Protection Team in accordance with Guidelines for the Public Health Management of Pertussis in England or PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings
	
	Healthcare Workers (HCWs) Immunisation
	HCWs aged 16 years and over who have not received a pertussis containing vaccine in the last 5 years and have regular contact with pregnant women or young infants for occupational vaccination according to the identified priority categories as follows;
	
	Priority group 1
	• HCWs with regular and close clinical contact with severely ill young infants and women in the last month of pregnancy. This includes:
	  ○ clinical staff working with women in the last month of pregnancy (for example midwifery, obstetrics and maternity settings)
	  ○ neonatal and paediatric intensive care staff who are likely to have close and or prolonged clinical contact with severely ill young infants.

	Priority group 2 • HCWs with regular clinical contact with young unimmunised infants in hospital or community settings. This includes: o general paediatric staff o paediatric cardiology staff o paediatric surgery staff o health visitor staff. **Priority group 3** • HCWs with intermittent clinical contact with young unimmunised infants in the community. This includes HCWs in general practice. **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. 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: • 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 • 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) • 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 month

	• Experienced transient thrombocytopenia, 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) 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. The Green Book advises that there are very few individuals who cannot receive diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/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. 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. If a child 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. 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, dTaP/IPV 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 dTaP/IPV is recommended by the local health protection team. The dTaP/IPV (Repevax® or 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 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. Where a dTaP/IPV vaccine has been administered to an individual who has not completed primary immunisation the dose of dTaP/IPV should be discounted.
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. 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.

	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. Inform or refer to the clinician in charge at the clinic or GP as appropriate. In the case of women who have received immunisation against pertussis, tetanus, diphtheria and/or poliomyelitis recently, the immunisation should be rearranged to ensure there is a gap of at least one month between doses. 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. Inform/refer to the relevant medical practitioner if individual/parent/carer declines treatment. 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	Diphtheria, tetanus, pertussis and poliomyelitis vaccine (dTaP/IPV) as either Repevax® or Boostrix®-IPV suspension for injection in a prefilled syringe.
Legal status	Repevax® or Boostrix®-IPV are Prescription-only Medicines (POM).
Is the use out with the SmPC?	Administration of Boostrix®-IPV by deep subcutaneous injection to individuals with a bleeding disorder is an off-label administration but may be considered where this remains in line with advice in Chapter 4 of The Green Book. 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.

	Administration to individuals who have experienced an encephalopathy of unknown origin within 7 days of previous vaccination with a pertussis-containing vaccine is off-label but may proceed once the cause is identified or the condition has been stabilized in accordance with the recommendations in Chapter 24 of Immunisation Against Infectious Disease: The Green Book. 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.
Dosage/Maximum total dose	0.5mL
Frequency of dose/Duration of treatment	**Routine Childhood Immunisation Schedule** The dTaP/IPV 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 at the scheduled visit 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 (See additional information section).

	Revaccination of individuals who have received a haemopoietic stem cell transplant: In accordance with the schedule recommended by the Scottish Haematology Society vaccination policy (Post HSC Transplantation): Scottish Haematology Society - Vaccination Policy (Post HSC Transplantation) (scothaem.org) **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 last 12 months may be given a single booster dose of diphtheria-containing vaccine. **Management of cases and contacts of pertussis** A single dose of dTaP/IPV should be administered to contacts recommended immunisation in accordance with Guidelines for the Public Health Management of Pertussis in England or PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings who have not received a dose of pertussis-containing vaccine in the last five years and no Td/IPV vaccine in the preceding month. A dTaP/IPV dose is recommended at any stage of pregnancy for pertussis contacts in Group 2 (b, c or d)[1], at increased risk

[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)

	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. **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.
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. 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. 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. 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.

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

	The vaccines should be given when possible in different limbs to allow monitoring of local reactions to dTap/IPV 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. Store in original packaging in order to protect from light. Do not freeze. 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. 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	**Pregnancy** Vaccination 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 to the baby. Women pregnant with twins or multiple pregnancies require a single dose of diphtheria, tetanus, pertussis and poliomyelitis vaccine. Women who become pregnant again while the programme is in place 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 using Boostrix®-IPV or Repevax® would not be required, refer to advice in The Green Book Chapter 30. Women who have never received (or not completed) a primary schedule of vaccination against diphtheria, tetanus and polio should be offered a single dose of dTaP/IPV in accordance with this PGD. They should then be offered Td/IPV (e.g. Revaxis®) at appropriate intervals if any subsequent doses of vaccine are needed to complete a three dose primary course. See PHE Vaccination of individuals with uncertain or incomplete immunisation status.
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 individual's GP should be contacted for advice.
Advice (Verbal)	• Advise individual/parent/carer what to expect and of the possible side effects and their management. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • 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. When administration is postponed, advise the individual/parent/carer when to return for vaccination. 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. Supply immunisation promotional material as appropriate. 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. 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. Common adverse reactions include fever, irritability, headache, nausea, diarrhoea, vomiting, rash, arthralgia, appetite loss, malaise, fatigue/asthenia, dermatitis, bruising and pruritus. 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.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) 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. 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: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • 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) • 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.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual/parent/carer's capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Familiar with the vaccine product and alert to changes in the product information

	• Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent in the handling and storage of vaccines, and management of the "cold chain" • 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:**
	• 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
	• 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. **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.
	• Have knowledge and familiarity of the following;
	  ○ Current edition of the Green Book
	  ○ SmPC for the vaccine to be administered in accordance with this PGD
	  ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board
	  ○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).

Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.

	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: Nurses, midwives and health visitors can be authorised by their line manager. 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. 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 must be completed to allow audit of practice. An electronic/Hospital Electronic Prescribing and Medicines Administration (HEPMA) record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD, it should include as a minimum:

	• Date and time of vaccine administration • Individuals name, address and CHI • GP with whom the individual is registered • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/and anatomical site of the vaccination administered • Advice given, including advice given if excluded or declined vaccination under this PGD • 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 • Where childhood immunisations are given, information of the administration must be provided to the GP Practice and Practitioner Services Division (PSD) for inclusion on the Scottish Immunisation Recall System (SIRS). • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner). 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. • Child Health Information Services if appropriate • BadgerNet – Digital Maternity Notes • Hand–held records such as red book if appropriate • Individual's GP records if appropriate • Occupational health systems • HEPMA • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner. 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 Boostrix®-IPV -IPV– Date of revision of text 06/11/20, accessed 13/07/22. Repevax® - Date of revision of text 22/07/21, accessed 13/07/22. British National Formulary for Children and the British National Formulary accessed 13/07/22. Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Tetanus: the green book, chapter 30 - GOV.UK (www.gov.uk) Polio: the green book, chapter 26 - GOV.UK (www.gov.uk) Pertussis: the green book, chapter 24 - GOV.UK (www.gov.uk) Diphtheria: the green book, chapter 15 - GOV.UK (www.gov.uk) 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 Diphtheria, Tetanus, Pertussis And Poliomyelitis Vaccine (dTaP/IPV) By Approved 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 his or her individual code of professional practice and conduct.
Patient Group Direction For The Administration of Diphtheria, Tetanus, Pertussis And Poliomyelitis Vaccine (dTaP/IPV) By Approved 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 Diphtheria, Tetanus, Pertussis And Poliomyelitis Vaccine (dTaP/IPV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**