This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Diphtheria, Tetanus, Acellular Pertussis and Inactivated Poliomyelitis Vaccine (dTaP/IPV)

By registered health care professionals for

Individuals from 3 years 4 months to under 10 years of age, in accordance with the national immunisation programme, or for the management of cases and contacts of diphtheria, tetanus or poliomyelitis from 3 years of age

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 84

1. Change history

Version number	Change details	Date
V01.00	New PHE PGD template	15/12/2015
V02.00	DTaP/IPV PGD routine review and amended to: • include vaccination in line with recommendations for the management of diphtheria or polio • remove exclusions regarding timing of previous vaccination (see dose section for schedules) • remove exclusions relating to neurological conditions and encephalopathy and relevant advice moved to the cautions section • update off-label section in relation to amended exclusions • update dose section with management of cases and contacts of polio and diphtheria • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD	29/09/2017
V03.00	dTaP/IPV PGD routine review and amended to: • removed the DTaP/IPV (Infanrix®-IPV) product as not currently marketed in the UK • include Boostrix®-IPV • include individuals identified by an Outbreak Control Team for immunisation in response to a school/nursery pertussis outbreak • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	22/10/2019

2. Medicines practice guideline 2: Patient group directions

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises **Additionally practitioners:** • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD)
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals from 3 years for the prevention of diphtheria, tetanus, pertussis and poliomyelitis, in accordance with the national immunisation programme and recommendations given in Chapter 15, Chapter 24, Chapter 26 and Chapter 30 of Immunisation Against Infectious Disease: "The Green Book" and associated disease management guidelines (see Dose and frequency of administration section)
Inclusion criteria	Individuals from 3 years 4 months to under 10 years of age who require a booster following a primary course of immunisation against diphtheria, tetanus, pertussis and poliomyelitis (this booster is usually offered from 3 years 4 months of age) Individuals from 3 years of age (see Additional information regarding individuals over 10 years) who: • have a tetanus prone wound and tetanus immunisation is recommended in accordance with PHE Tetanus 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 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 • are identified by an Outbreak Control Team for immunisation in response to a school/nursery pertussis outbreak, in accordance with the PHE Guidelines for the Public Health Management of Pertussis in England
Exclusion criteria	Individuals for whom no valid consent has been received. 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, neomycin and bovine serum albumin (refer to relevant SPC) • have not yet completed primary immunisation with three doses of diphtheria, tetanus, pertussis and poliomyelitis antigen unless recommended by an Outbreak Control Team • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

Cautions (including any relevant action to be taken)	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 is identified or the child recovers within 24 hours. However, if no underlying cause has been 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 PHE Tetanus Guidance on the management of suspected tetanus cases and on the assessment and management of tetanus-prone wounds)
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded *(continued)*	• Patient should be referred to a more experienced clinical practitioner for further assessment • Individuals who have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis and poliomyelitis vaccine, or any components of the vaccine, should be referred to a clinician for specialist advice and appropriate management • If the individual has not yet completed primary immunisation with three doses of diphtheria, tetanus, pertussis and

Action to be taken if patient excluded *(continued)*	poliomyelitis antigen provide priming doses of DTaP/IPV/Hib/HepB as required (see DTaP/IPV/Hib/HepB PGD) • In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged • Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician where appropriate • The risk to the individual of not being immunised must be taken into account • Document the reason for exclusion and any action taken in the individual's clinical records • Inform, or refer to, the GP or a prescriber as appropriate
Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications • Inform or refer to the GP as appropriate

8. Details of the medicine

Name, form and strength of medicine	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed): • Repevax®, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV • Boostrix®-IPV, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV
Legal category	Prescription Only Medicine (POM)
Indicate any <u>off-label use</u> (if relevant) *(continued)*	• 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 <u>Chapter 4</u> of the 'Green Book'. Alternatively, 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 <u>SPC</u>. Note: The Repevax® SPC 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

Indicate any off-label use (if relevant) *(continued)*	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" • The vaccine product SPCs do not make reference to use of dTaP/IPV for the management of outbreak, cases or contacts but do include use of the vaccine as a booster and state that the vaccine should be administered in accordance with official recommendations. Vaccination is therefore recommended under this PGD in accordance with the relevant chapters of the Green Book and associated PHE guidelines (see Dose and frequency of administration • 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 PHE 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 • Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence
Route/method of administration	• Administer by intramuscular injection, preferably into deltoid region of the upper arm • For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the 'Green Book' Chapter 4 or the product's SPC (see Off-label use section) • See Appendix C for more information
Dose and frequency *(continued)*	Single 0.5ml dose per administration **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 DTaPcontaining 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

Dose and frequency *(continued)*	**Management of tetanus prone wound:** • Individuals with incomplete or uncertain history of tetanus immunisation should be vaccinated in accordance with the recommendations in the "The Green Book" Chapter 30 Table 30.1 and PHE Tetanus 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 pertussis outbreak in a school/nursery:** Cases and contacts of pertussis in a school/nursery outbreak should be managed in accordance with PHE Guidelines for the Public Health Management of Pertussis in England and recommendations from the Outbreak Control Team **Management of cases and contacts of polio:** • Cases and contacts of polio should be managed in accordance with PHE 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
Quantity to be administered and/or supplied	Single 0.5ml dose per administration
Maximum or minimum treatment period	• A single booster dose • Other diphtheria, tetanus, pertussis and polio vaccines are recommended for primary immunisation (that is DTaP/IPV/Hib/HepB) and subsequent boosters (that is the Td/IPV adolescent booster) to complete immunisation in accordance with national recommendations

Storage	• Store at +2°C to +8°C • Store in original packaging in order to protect from light • Do not freeze • 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, refer to PHE Vaccine Incident Guidance
Adverse effects	• Local reactions following vaccination are very common ie pain, swelling or redness at the injection site. 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 • Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare • A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium website:www.medicines.org.uk
Records to be kept	• The administration of any medication given under a PGD must be recorded within the patient's medical records • See Appendix C for more information

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request • Immunisation promotional material may be provided as appropriate: Pre-school immunisations: guide to vaccinations (2 to 5 years) Available from: www.gov.uk/government/collections/immunisation
Follow-up advice to be given to patient or carer	• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • Inform the individual/carer/parent of possible side effects and their management • The individual/carer/parent should be advised to seek medical advice in the event of an adverse reaction • When administration is postponed advise the individual/carer/parent when to return for vaccination

10. Appendix A

References

1. British National Formulary (BNF) 2019 available online: https://bnf.nice.org.uk
2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk

DTaP/IPV and dTaP/IPV vaccine

- Immunisation Against Infectious Disease: The Green Book Chapter 15, Chapter 26 and Chapter 30. Last updated 19 April 2013. Chapter 24. Last updated 7 April 2016 https://www.gov.uk/government/collections/immunisation-against- infectious-disease-the-green-book
- Summary of Product Characteristic for Repevax®, Sanofi Pasteur. 7 April 2019. http://www.medicines.org.uk/emc/medicine/15256
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- PHE national polio guidelines: Local and regional services. Public Health England. 26 September 2019. https://www.gov.uk/government/publications/polio-national- guidelines

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- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimumstandards-and-core-curriculum-for-immunisation-training-forregistered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources
- PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation
- PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incidentguidance-responding-to-vaccine-errors

11. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

12. Appendix C

Route/method of administration	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. 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 not be used if discoloured or foreign particles are present in the suspension. The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)
Drug interactions	• Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited • May be given at the same time as other vaccines • A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

Records to be kept	• that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of vaccinator • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines vaccination • details of any adverse drug reactions and actions taken • supplied via PGD • Records should be signed and dated (or a password-controlled vaccinator's record on e-records) • All records should be clear, legible and contemporaneous • This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. • The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy
Special considerations/ additional information *(continued)*	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination • Individuals should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes • 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 referred to their GP for immunisation in accordance with Vaccination of individuals with uncertain or incomplete immunisation status algorithm. Where a dTaP/IPV vaccine has been administered to an individual who has not completed primary immunisation the dose of dTaP/IPV should be

Special considerations/ additional information *(continued)*	discounted • 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 for a cohort identified by an Outbreak Control Team • Pertussis vaccination may be recommended for individuals over 10 years of age under inclusion criteria not covered by this PGD (see PHE Pertussis PGD) • Tetanus vaccine given at the time of a tetanus-prone injury may not boost immunity early enough to give additional protection within the incubation period of tetanus. Therefore, tetanus vaccine is not considered adequate for treating a tetanus-prone wound. However, this provides an opportunity to ensure that the individual is protected against future exposure. Individuals may also require human tetanus immunoglobulin (see the 'Green Book' Chapter 30) • If a person has received vaccination for a tetanus-prone wound, or as a case or contact of diphtheria, tetanus or polio, with the same vaccine as due for routine immunisation and it was administered at an appropriate interval then the routine immunisation dose may not be required