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 and Inactivated Poliomyelitis Vaccine (Td/IPV)

By registered health care professionals for

Individuals from 10 years of age, in accordance with the National Immunisation Programme, for travel, have a tetanus prone wound or for the management of cases and contacts of diphtheria, tetanus or poliomyelitis

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

PGD NUMBER 140

1. Change History

Version number	Change Details	Date
V01.00	New PHE PGD template	16/10/2015
V02.00	Td/IPV (Revaxis®) 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, encephalopathy and Guillain Barre/brachial neuritis and relevant advice moved to the cautions section • update off-label section in relation to amended indications • 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 templates	29/09/2017
V03.00	Td/IPV (Revaxis®) PGD routine review and amended to: • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	12/09/2019

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 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 PGD's
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
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 10 years of age for the prevention of diphtheria, tetanus and poliomyelitis, in accordance with the national immunisation programme and recommendations given in Chapter 15, Chapter 26 and Chapter 30 of Immunisation Against Infectious Disease: 'The Green Book'.

Inclusion criteria	Individuals aged 10 years and over who:
	• require a booster following a primary course of immunisation against diphtheria, tetanus and poliomyelitis (this booster is usually offered at 13 to 18 years of age, unless the course has already been completed)
	• have no history or an incomplete history of diphtheria, tetanus or poliomyelitis immunisation
	• are travelling to an area where medical attention may not be accessible should a tetanus prone wound occur, or will be residing in epidemic or endemic areas where tetanus, diphtheria or poliomyelitis protection is required, and the final dose of the relevant antigen was received more than 10 years ago, even if the individual has received 5 doses of tetanus containing vaccine previously
	• have a tetanus prone wound and one or more of the following apply (see Green Book Chapter 30):
	  ○ primary tetanus immunisation is incomplete
	  ○ tetanus boosters are not up to date or last dose of tetanus containing vaccine was more than 10 years ago
	  ○ tetanus immunisation status is unknown or uncertain
	  ○ individual has never received tetanus immunisation
	• require vaccination in line with recommendations for the management of cases and contacts of diphtheria or polio

Exclusion criteria[2]	Individuals for whom no valid consent has been received. Individuals who: • are aged less than 10 years • have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus or poliomyelitis containing vaccine, including any conjugate vaccines where diphtheria or tetanus toxoid is used in the conjugate • have had a confirmed anaphylactic reaction to any component of the vaccine, including neomycin, streptomycin or polymyxin B • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Cautions (including any relevant action to be taken)	• Td/IPV may be given to pregnant women when protection is required without delay, such as following a tetanus prone wound. However, pregnant women from week 16 of pregnancy onwards should instead be protected by the administration of the routinely indicated dTaP/IPV (see Pertussis PGD) • 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. Where possible, vaccination should be postponed until immune function has recovered. However, vaccination of subjects with chronic immunodeficiency, such as AIDS, is recommended even if the antibody response might be limited
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	• Patient should be referred to a more experienced clinical practitioner for further assessment • If aged under 10 years assess for immunisation with DTaP/IPV/Hib/HepB, DTaP/IPV or dTaP/IPV as appropriate • 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 as 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 • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration

8. Details of the medicine

Name, form and strength of medicine	Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV): • Revaxis®, suspension for injection in a pre-filled syringe.
Legal category	Prescription Only Medicine (POM)
Indicate any off-label use (if relevant)	• Primary immunisation is off-label administration in accordance with the recommendations given for individuals over 10 years of age in Chapter 15, Chapter 26 and Chapter 30 of Immunisation Against Infectious Disease: 'The Green Book' • Administration to individuals who have received a vaccine containing diphtheria or tetanus toxoids within the previous five years is off-label but indicated for the management of primary immunisation (as above) and for cases and contacts of diphtheria or polio in accordance with PHE disease management guidelines (see Dose and frequency of administration) • Administration to individuals who experienced neurological complications following an earlier immunisation against diphtheria and/or tetanus is off-label but may proceed once the cause is identified, the condition has been stabilized or the expected course of the condition becomes clear in accordance with the recommendations in Chapter 15 and Chapter 30 of 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 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/parent/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 • 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 • 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. • The vaccine's normal appearance is a cloudy white suspension that may sediment during storage. Shake the pre-filled syringe well to distribute uniformly the suspension before administering the vaccine. • The vaccine should not be used if foreign particles are present in the suspension. • The SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk
Dose and frequency *(continued)*	Single 0.5ml dose per administration **Routine childhood immunisation schedule** Td/IPV is routinely offered to teenagers as a second booster dose at around 14 years of age. It should ideally be given 10 years after the first booster dose. It should be given at the school session or scheduled appointment provided a minimum of 5 years have elapsed between the first and second boosters. (Note: the first booster is usually given at pre-school age using dTaP/IPV or DTaP/IPV (Repevax® or Infanrix®-IPV)) **UK immunisation schedule for previously unimmunised individuals or where there is an unknown or incomplete history of diphtheria, tetanus and poliomyelitis vaccination** • Individuals with uncertain or incomplete diphtheria, tetanus and poliomyelitis vaccine history should be vaccinated in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart • The primary course consists of three doses, allowing an interval of one month between doses. Where a primary course is interrupted it should be resumed but not repeated • A first booster dose should be administered at least 5 years after the third dose of the primary course • A second booster dose should be administered a minimum of 5 years, ideally 10 years, after the first booster dose, if less than 5 doses of diphtheria, tetanus and polio vaccine are documented

Dose and frequency *(continued)*	**Travel immunisation** • Individuals travelling should be vaccinated in accordance with the UK schedule • A single booster dose may be indicated for fully immunised individuals whose last dose of vaccine was more than 10 years ago (see https://travelhealthpro.org.uk/). **Management of tetanus prone wound** • Individuals with a tetanus prone wound who received their last dose of tetanus containing vaccine more than 10 years ago should receive a reinforcing dose of vaccine • 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 • Individuals may also require human tetanus immunoglobulin (see 'Green Book' Chapter 30). 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 should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes • Unimmunised individuals should receive three doses at monthly intervals • Individuals who are fully immunised but have not received diphtheria containing vaccine in last 12 months may be given a single reinforcing dose of Td/IPV **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 and recommendations from the local health protection team • Individuals should have their immunisation status checked to ensure they are up to date with the recommended UK immunisation programmes • 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 **Points to note** • Where there is no reliable history of previous immunisation, it should be assumed that individuals are unimmunised and the full UK recommendations should be followed • Where children have had a fourth dose of tetanus, diphtheria

Dose and frequency *(continued)*	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. The routine pre-school and subsequent boosters should be given according to the UK schedule • If a person attends for a routine booster dose and has a history of receiving a vaccine following a tetanus-prone wound, attempts should be made to identify which vaccine was given. If the vaccine given at the time of the injury was the same as that due at the current visit and was given after an appropriate interval, then the routine booster dose is not required. Otherwise, the dose given at the time of injury should be discounted as it may not provide long- term protection against all antigens, and the scheduled immunisation should be given. Such additional doses are unlikely to produce an unacceptable rate of reactions
Quantity to be administered	As per dose
Maximum or minimum treatment period	• A total of 5 doses (3 primary course doses and 2 booster doses) of diphtheria, tetanus and polio vaccine are indicated for complete immunisation (doses provided under the age of 10 years will not be provided using this vaccine) • A further booster dose may be indicated 10 years after the final dose where risk of exposure is high • A reinforcing dose may be recommended following potential exposure
Storage	• Store at +2°C to +8°C. • Store in original packaging 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 *(continued)*	• Local reactions following vaccination are very common such as pain, swelling or redness at the injection site. A small painless nodule may form at the injection site • Common adverse reactions include pyrexia, headache, vertigo, nausea and vomiting • Allergic reactions can occur including generalised skin reactions such as urticaria, anaphylactic reactions, angioedema and shock. • A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme (http://yellowcard.mhra.gov.uk)

Adverse effects *(continued)*	• Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed
Records to be kept	The administration of any medication given under a PGD must be recorded within the patients' medical records Please see Appendix C for more details.

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
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 • When administration is postponed advise the individual/carer/parent when to return for vaccination

10. Appendix A

References

1. British National Formulary (BNF) 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

Td/IPV vaccine (Revaxis®)

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- Summary of product characteristic for Revaxis®, Sanofi Pasteur. 4 January 2018. www.medicines.org.uk http://www.medicines.org.uk/emc/medicine/15259
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- Public health control and management of diphtheria (in England and Wales) guidelines. Public Health England. 24 March 2015. https://www.gov.uk/government/publications/diphtheria-public- health-control-and-management-in-england-and-wales

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- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe- management-of-healthcare-waste
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum- standards-and-core-curriculum-for-immunisation-training-for- registered-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-incident- guidance-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

Special considerations/ additional information	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. • 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. • Intravenous drug users are at greater risk of tetanus. Every opportunity should be taken to ensure that they are fully protected against tetanus. Booster doses should be given if there is any doubt about their immunisation status.
Records	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • 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 immunisation • details of any adverse drug reactions and actions taken • supplied via PGD • Records should be signed and dated (or a password-controlled immuniser'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