

PATIENT GROUP DIRECTION

Administration of Combined low-dose Diphtheria, Tetanus, and Inactivated Polio vaccine Td/IPV for Children over 10 years of age, Adolescents and Adults
by Registered Nurses
to patients registered with General Practitioners within NHS Cambridgeshire

Issue date: 1st December 2011

Supercedes: PGD for Administration of Combined low-dose Diphtheria, Tetanus, and Inactivated Polio vaccine Td/IPV for Children over 10 years of age, Adolescents and Adults (expired November 2011)

Expiry date: 31st October 2013, or earlier in the light of local or national changes

Developed & produced by:

Name	Designation/Title	Signature	Date
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Penny Miller	Immunisation Coordinator NHSC	Signed on	29.11.2011
June Grainger	Practice Nurse	Signed on	30.11.2011
Roisin Wright	Medicines Management Nurse Specialist NHSC	Signed on	30.11.2011

This patient group direction has been approved on behalf of NHS Cambridgeshire by:

Name	Designation/Title	Signature	Date
Sati Ubhi	Deputy Chief Pharmacist	Signed on	07.12.2011
Dr Christine Macleod	Medical Director	Signed on	05.12.2011

Authorisation of Employer (if not employed by NHS Cambridgeshire):

Name	Designation/Title	Signature	Date

Patient Group Direction for Administration of Combined low-dose Diphtheria, Tetanus, and Inactivated Polio vaccine Td/IPV for Children over 10 years of age, Adolescents and Adults

Action required before proceeding with administration and/or supply of a vaccine /medication under this Patient Group Direction

Each registered practitioner authorised to administer medication under this PGD must have read, understood and signed this version of the PGD and completed the agreement to practice form before attempting to work to it.

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence.

It is the responsibility of each individual practitioner to confirm before each administration that the information within this PGD is 'up-to-date'.

In the event that the information links no longer work, or the PGD has expired, please notify NHS Cambridgeshire's Medicines Management Team. In such circumstances a Patient Specific Direction (PSD) is indicated.

In order for administration and/or supply of the vaccine/medication under this PGD to be valid, practitioners should have electronic access to, or a hard copy of, the most recent information relating to the named vaccine:

- **Childhood Immunisation Schedule** (Department of Health, 2010), available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_122401.pdf
- **Relevant chapter(s) of 'The Green Book' – Immunisation against infectious disease** (Department of Health, 2006), available via http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917
- **Summary of Product Characteristics from the electronic Medicines Compendium (eMC)**, available via <http://www.medicines.org.uk/EMC/default.aspx>
- **British National Formulary**, available online at <http://bnf.org/bnf/bnf/current/> (Athens login required)
- **Patient information leaflets from the electronic Medicines Compendium (eMC)**, available via <http://www.medicines.org.uk/EMC/default.aspx>

Vaccination information for members of the public (NHS Choices, 2011), is available at <http://www.nhs.uk/Planners/vaccinations/Pages/Landing.aspx>

Further immunisation information for health care professionals (Department of Health, 2011), is available at <http://www.dh.gov.uk/en/Publichealth/Immunisation/index.htm>

Further information relating to Healthcare professional reporting adverse reactions (MHRA, 2011), is available at <http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspectedadversedrugreactions/Healthcareprofessionalreporting/Adversedrugreactions/index.htm>

The original copy, signed by all those concerned, should be kept in a designated safe place within the practice, and readily accessible to all registered nurses for reference.

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1. Characteristics of Staff	
1.1 Professional qualification	This PGD is agreed for use by Registered Nurses undertaking immunisation/vaccination
1.2 Additional requirements	<ul style="list-style-type: none"> • Resuscitation skills & anaphylaxis training • Competent to undertake immunisations <p>All authorised staff must demonstrate an appropriate level of understanding and knowledge with regards to:</p> <ul style="list-style-type: none"> • Assessment of patient • The medication, therapeutic use, contraindications, side-effects, interactions and storage and handling requirements • Be familiar with relevant NHSC medicines policies • Have access to local and national guidance as outlined on page 2
1.3 Continued training requirements	<ul style="list-style-type: none"> • Annual attendance at the PCT or workplace update on resuscitation skills and the management of anaphylaxis within the community • Maintenance of own level of updating with evidence of continued professional development (PREP requirements)
2. Clinical condition or situation to which the direction applies	
2.1 Indication	<ul style="list-style-type: none"> • Active immunisation against diphtheria, tetanus and poliomyelitis
2.2 Criteria for inclusion	<p>Children aged 10 years or over or adults who need:</p> <ul style="list-style-type: none"> • A booster vaccination against diphtheria, tetanus and poliomyelitis • To complete a primary course of immunisation against diphtheria, tetanus or poliomyelitis • A primary course in previously unimmunised individuals or where there is unreliable history of previous immunisation against diphtheria, tetanus or poliomyelitis • Vaccination following a clean wound depending on the immunisation status of the patient • Patients with tetanus prone wounds should be given tetanus vaccine and/or immunoglobulin (as per Green Book) and then, after assessment, referred to the Accident and Emergency Department for appropriate treatment if considered necessary • Additional protection against diphtheria, tetanus or polio for travellers to epidemic or endemic areas whose final dose of the relevant antigen was received more than 10 years ago <p>For further details please refer to the BNF, Green Book and SPC or contact the manufacturer</p> <p>Also visit the website of the Health Protection Agency (HPA) at http://www.hpa.org.uk/web/HPAweb_C/1194947406156 for further details about 'Vaccination of Individuals with Uncertain</p>

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	<p>or Incomplete Immunisation Status'</p> <p>For individuals coming from other countries, please visit WHO – World Health Organisation country-by-country vaccination schedules and coverage information online at http://www.who.int/vaccines/globalsummary/immunisation/countryprofilesselect.cfm</p>
<p>2.3 Criteria for exclusion</p>	<p>The following individuals should be excluded:</p> <ul style="list-style-type: none"> • No valid consent • Acute febrile/infectious illness – postpone and reschedule (except in the presence of tetanus prone wounds, in which case the patient should be referred to the Accident and Emergency Department for appropriate treatment) • History of a confirmed anaphylactic reaction to a previous dose of this vaccine, or a previous dose of diphtheria, tetanus, pertussis and inactivated polio containing vaccine • History of a confirmed anaphylactic reaction to neomycin, streptomycin or polymixin B • History of a confirmed anaphylactic reaction to any component of the vaccine • Children aged less than 10 years old • Individuals over 10 years old who have not completed a primary course of immunisation. Department of Health advice is that Revaxis ® can be given, but this use is unlicensed – a prescription is required • Progressive, evolving or unstable evidence of a neurological condition (see relevant chapters of the Green Book) • Neurological abnormalities following immunisation (see Green Book chapters and flow chart). You must discuss the case with a doctor and obtain a written Patient Specific Direction if administering the vaccine to an individual with a history of neurological abnormality following immunisation <p>NB Patients may be excluded by cautions or interactions</p> <p><i>Where there is doubt, appropriate advice should be sought from a consultant paediatrician, immunisation coordinator or consultant in communicable disease control, rather than withhold immunisation. Specialist advice must be sought on the vaccines and circumstances in which they could be given</i></p> <p style="text-align: center;">The risk to the individual of not being immunised must be taken into account</p> <p>For further details please refer to the Green Book and the SPC and/or contact the manufacturer</p>
<p>2.4 Action if excluded</p>	<ul style="list-style-type: none"> • Offer advice on when individuals may have the vaccine • Discuss with the patient/client/guardian and document the reasons for exclusion from treatment under the PGD • Reschedule or refer/transfer to the appropriate prescriber/service as soon as clinically appropriate

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	<ul style="list-style-type: none"> Specialist advice must be sought on the vaccine/medication and circumstances under which they could be given The risk to the individual of not being immunised must be taken into account
2.5 Action if patient declines treatment	<ul style="list-style-type: none"> Advise about protective effects of the vaccine/medication and the risks of infection and disease complications. Document refusal and advice given in the patient record Inform or refer to GP as appropriate Arrange alternative appointment for an individual suffering febrile illness or who is systemically unwell Offer disease avoidance advice if travelling
2.6 Reasons for referral or seeking medical advice	<ul style="list-style-type: none"> Exclusions or patient/guardian preference Emergency treatment of anaphylactic reactions – Guidelines for Healthcare Providers – Resuscitation Council UK available online at http://www.resus.org.uk/pages/reaction.pdf with the following algorithm http://www.resus.org.uk/pages/anaalgo.pdf In the event of an adverse reaction refer for medical advice If there are any concerns or cautions/interactions relating to the medicine to be given, practitioners should seek medical advice or refer/transfer to the appropriate prescriber/service if necessary
3. Description of Treatment	
3.1 Name, strength & formulation of drug	Revaxis ® vaccine (Sanofi Pasteur MSD) – Combined low-dose diphtheria, tetanus, and poliomyelitis (inactivated) vaccine (Td/IPV)
3.2 Legal status	POM (Prescription Only Medicine)
3.3 ▼ Black triangle?	No
3.4 PGD covering use outside terms of Summary of Product Characteristics?	<p>Yes – Revaxis ® is not licensed for primary immunisation. However, the JCVI recommends that Td/IPV may be used for a primary vaccination course for individuals aged 10 years or over who were previously unimmunised or where there is an incomplete or no history of previous vaccination against diphtheria, tetanus or poliomyelitis vaccines</p> <p>A complete history would be a primary course of 3 doses at 1 month intervals, a booster at least 5 years after the primary course and again 10 years later (5 doses in total)</p>
3.5 Route/method of administration	<ul style="list-style-type: none"> Revaxis ® vaccine can be given at the same time as other vaccines but at a different injection site – preferably in different limbs, or if given in the same limb they should be given at least 2.5cms apart Revaxis ® vaccine should be administered via the intramuscular route except where there is a bleeding disorder when the deep subcutaneous route should be used
3.6 Dose	0.5ml

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<p>3.7 Frequency of administration</p>	<ul style="list-style-type: none"> • A booster dose of Td/IPV should be administered to children aged over 10 years old, adolescents or adults: • 3 years after the primary course (this interval can be reduced to a minimum of 1 year if the primary course was delayed) • 10 years after the first booster dose (this interval can be reduced to a minimum of 5 years if the previous doses were delayed) • Travel to areas with a risk of diphtheria infection should receive a further booster dose if more than 10 years has lapsed since completion of the UK vaccination schedule • Unimmunised individuals 10 years and over should receive a primary course of 3 doses Td/IPV, followed by booster vaccinations as above • All individuals should receive a total of 5 doses of diphtheria, tetanus and polio containing vaccines to ensure long-term protection through adulthood • Individuals who have not completed the 5 doses should have their remaining doses at the appropriate interval • Where there is an unclear history of vaccination, adults should be assumed to be unimmunised. A full course of diphtheria, tetanus and polio should be offered in line with advice contained in the relevant chapters of the Green Book <p>For further details refer to:</p> <ul style="list-style-type: none"> • The BNF, Green Book and SPC or contact the manufacturer • The Health Protection Agency (HPA) at http://www.hpa.org.uk/web/HPAweb_C/1194947406156 for further details about 'Vaccination of Individuals with Uncertain or Incomplete Immunisation Status' • For individuals coming from other countries, please visit WHO – World Health Organisation country-by-country vaccination schedules and coverage information or seek advice from the Immunisation Coordinator prior to the patient's attendance for vaccination
<p>3.8 Cautions</p>	<ul style="list-style-type: none"> • If Guillain-Barre syndrome or brachial neuritis has occurred following receipt of prior vaccine containing tetanus toxoid, the decision to give any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks • The immunisation with tetanus-containing vaccine should continue following a history of: <ul style="list-style-type: none"> - Fever, irrespective of its severity - Hypotonic-hyporesponsive episodes (HEE) - Persistent crying for more than 3 hours - Severe, local reaction, irrespective of extent • Individuals who have had severe reactions, as above, have continued and completed immunisation with tetanus-containing vaccines without recurrence (Vermeer-de Bondt et al., 1998; Gold et al., 2000) • If there is evidence of current neurological deterioration,

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	<p>including poorly controlled epilepsy, immunisation should be deferred and the child should be referred to a child specialist for investigation to see if an underlying cause can be identified</p> <ul style="list-style-type: none"> • If a cause is not identified, immunisation should be deferred until the condition has stabilised • If a cause is identified, immunisation should proceed as normal • A family history of seizures is not a contraindication to immunisation • Immunosuppression and HIV infection – individuals with immunosuppression or HIV infection (regardless of CD4 count) should be given tetanus-containing vaccines in accordance with the recommendations above. These individuals may not make a full antibody response • Re-immunisation should be considered after treatment is finished and recovery has occurred • Specialist advice may be required • Further guidance is provided by the Royal College of Paediatrics and Child Health (www.rcpch.ac.uk), the British HIV Association (BHIVA) Immunisation guidelines for HIV-infected adults (BHIVA, 2006) and the Children's HIV Association of the UK and Ireland (CHIVA) Immunisation guidelines (www.bhiva.org/chiva) <p>Please refer to the Green Book for further details and if appropriate and/or not sure please seek expert immunisation advice</p>
<p>3.9 Interactions with other medicines See also any interactions listed as exclusions</p>	<ul style="list-style-type: none"> • See the Green Book, SPC and BNF and/or contact the manufacturer • The immunogenicity of the vaccine may be reduced by immunosuppressive treatment or immunodeficiency • The vaccine should not be mixed with other vaccines in the same syringe/needle
<p>3.10 Special Considerations / Additional Information</p>	<ul style="list-style-type: none"> • Individuals with immunosuppression and/or HIV infection should be given Revaxis ® in accordance with the routine recommended schedule. These individuals may not make a full antibody response. Re-immunisation should be considered after treatment has finished and recovery has occurred. Seek specialist advice for re-immunisation decision and obtain written Patient Specific Direction • Pregnancy and breastfeeding – the Joint Committee on Vaccination and Immunisation (JCVI) advise that pregnant women and those who are breastfeeding can be immunised with Td/IPV when clinically indicated. There is no evidence from vaccinating pregnant women or those who are breastfeeding with inactivated viral or bacterial vaccines or toxoids • Additional considerations in case of a tetanus-prone injury: <ul style="list-style-type: none"> – For those whose immunisation status is uncertain, and individuals born before 1961 who may not have been

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	<p>immunised in infancy, a full course of immunisation is likely to be required – refer to Independent Prescriber</p> <ul style="list-style-type: none"> • For further details please refer to the Green Book
3.11 Identification & Management of Adverse Drug Reactions	<ul style="list-style-type: none"> • Very common – local reactions (injection site pain, erythema, induration and oedema), headache, nausea, arthralgia/joint swelling, myalgia, fever (lower than 38°C) • Common – pyrexia, nausea, vomiting, vertigo, headache • Rare – arthralgia • Very rare – inconsolable crying, high fever (higher than 40.5°C) • Anaphylaxis • Hypotonic-hyporesponsive episode (HHE) may occur, usually 1-12 hours after vaccination, and may last for a few minutes <ul style="list-style-type: none"> • For further details please refer to the MHRA website at http://www.mhra.gov.uk/SafetyinformationGeneralsafetyinformationandadvice/Product-specificinformationandadvice/Vaccinesafety/Othervaccinetopics/index.htm or to the SPC and/or contact the manufacturer
3.12 Reporting procedure of Adverse Drug Reactions	<ul style="list-style-type: none"> • Report any suspected ADR to a medical practitioner as soon as possible • Patients with unusual or persistent side effects should be reviewed by the GP • Any serious adverse reaction to the vaccine/medication should be documented in a child's health records and on their medical records. GP should also be informed. • For established medicines, report all serious suspected reactions in adults, and all serious AND minor reactions in children (under 18 years) via the Yellow Card reporting scheme • For medicines showing the black triangle ▼ symbol ALL suspected ADRs should be reported via the Yellow Card reporting scheme
3.13 Patient advice	<ul style="list-style-type: none"> • Inform possible side effects and their management • Give advice on temperature control • Always provide the manufacturers Patient Information Leaflet and any specific local/national leaflets to patient/parent/guardian as appropriate. Where a vaccination is given outside of the terms of the Summary of Product Characteristics, discuss and document in the patient's records • Explain treatment and any further instructions to aid compliance/concordance • Advise the patient/patient/guardian to seek medical advice in case of severe or unexpected adverse events • Refer to the Green Book and SPC for further details
3.14 Follow up treatment	<ul style="list-style-type: none"> • Not applicable
3.15 Storage and Handling	<ul style="list-style-type: none"> • Vaccine should be maintained at a temperature of +2° to +8°C. If the vaccine has been frozen, the vaccine

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	<p>should be discarded</p> <ul style="list-style-type: none"> • Store in the original package in order to protect from light • Disposal should be by incineration at a suitably authorised facility • Before use, nurses should satisfy themselves that the vaccine has been properly stored and that the cold chain has not been broken
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Please note:

Listed above are the interactions with commonly used medicines and the main side effects. If the patient/client is taking a medicine not listed above or reports side effects refer to the current BNF, Patient information Leaflet or electronic Medicines Compendium <http://www.medicines.org.uk/emc/default.aspx> or seek advice from pharmacist or medicines information department

4. Facilities and supplies that must be available	
4.1 Medicine to be stocked	Revaxis ® vaccine (<i>Sanofi Pasteur MSD</i>) – Combined low-dose diphtheria, tetanus, and Poliomyelitis (inactivated) vaccine (Td/IPV)
4.2 Storage	<ul style="list-style-type: none"> • Lockable monitored medicines refrigerator maintained between +2°C and +8°C
4.3 Reporting incidents	<ul style="list-style-type: none"> • Incidents and near misses must be reported using the NHS Cambridgeshire Incident Reporting form (DATIX), which should be forwarded to the Risk Manager as soon as possible AND/OR • Via employer’s critical incident reporting system
4.4 Other requirements	<ul style="list-style-type: none"> • Working telephone and/or access to emergency assistance • Anaphylaxis policy • Immediate access to Epinephrine (Adrenaline) 1in 1000 injection • Current BNF • Access to National Guidance – eg Green Book • Access to SPC • Supplies of Patient Information Leaflets
5. Records to be kept for audit purposes	
5.1 Patient details	<ul style="list-style-type: none"> • Patient identifiers • Allergies • Any reason for exclusion and action taken • Document patient consent or refusal • Advice sought from medical/specialist service • Details of any adverse reactions experienced by the patient and action taken • Verbal and written advice given to patient • Follow up and referral details
5.2 Records of administration	<ul style="list-style-type: none"> • In all cases manual records and computer records should include : <ul style="list-style-type: none"> ○ Patient’s name and date of birth

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	<ul style="list-style-type: none"> ○ Dose, site and route of injection/medication ○ Brand, batch number and expiry date of vaccine ○ Date given and by whom ○ Consent given and if a child by whom <p>Where vaccination is given to a child, this should also be recorded in the Child Health Record (PCHR red book)</p>
5.3 Audit	<ul style="list-style-type: none"> • Annual audit must be carried out by the clinical lead or nominated deputy within each practice • A computer or manual record of all individuals receiving immunisation under this Patient Group Direction should also be kept for audit purposes within each practice • Regulations require that there is a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient-by-patient basis • Audit may include evidence of authorised practitioner signatures, appropriate supply, standards of documentation, follow-up arrangements, advice and information given to patients, reporting of adverse effects and incidents

6. References

Department of Health (2006) **The Green Book – Immunisation against infectious disease**, available online at

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917 (accessed 16.11.2011).

Department of Health (2010) **Childhood Immunisation Schedule**, available online at

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_122401.pdf (accessed 26.11.2011).

Department of Health (2011) **Immunisation information for health care professionals**, available online at <http://www.dh.gov.uk/en/PublicHealth/Immunisation/index.htm> (accessed 26.11.2011).

Electronic Medicines Compendium (2011) **Summary of Product Characteristics for Revaxis®** (Sanofi Pasteur MSD Limited) last updated on the eMC website 22.05.2008, available online at <http://www.medicines.org.uk/EMC/medicine/15259/SPC/REVAXIS/> (accessed 16.11.2011).

Health Protection Agency (HPA) (2011) **Vaccination Immunisation**, available online at http://www.hpa.org.uk/infections/topics_az/vaccination/vac_guidelines.htm (accessed 26.11.2011).

Medicines and Healthcare products Regulatory Agency (MHRA) (2011) **Healthcare professional reporting: Adverse drug reactions**, available online at <http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspectedadversedrugreactions/Healthcareprofessionalreporting/Adversedrugreactions/index.htm> (accessed 26.11.2011).

NHS Choices (2011) **Vaccinations: Your NHS guide to vaccinations for you and your family**, available online at <http://www.nhs.uk/Planners/vaccinations/Pages/Landing.aspx> (accessed 26.11.2011).

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Resuscitation Council (UK) (2008) **Emergency treatment of anaphylactic reactions: Guidelines for healthcare providers**, available online at <http://www.resus.org.uk/pages/reaction.pdf> (accessed 26.11.2011).

AGREEMENT BY HEALTH PROFESSIONAL TO ACT UNDER THE PATIENT GROUP DIRECTION

I have read and fully understand the following:

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Issue date: 1st December 2011

Expiry Date : 30th November 2013

BNF and SPC monographs (and for Immunisation & Vaccination, the appropriate chapters of the Green Book) for all drugs included in this PGD.

NHS Cambridgeshire Patient Group Direction Policy

- I agree to act within the terms of the Patient Group Direction and administer and/or supply medicines in accordance with the documents listed above.
- I understand that my employer e.g. GP practice or NHS Cambridgeshire, is vicariously liable for acts and omissions by me during my employment with them.
- I understand that failure to comply with the terms and conditions of the PGD, including the expiry date and limitations on practitioners, patients, drugs and indications may render me liable to disciplinary action by my employer e.g. GP practice or NHSC under their performance and conduct arrangements.

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTICE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE

Name: *(block capitals)* (Health Professional)

Signature: (Health Professional)

Position:

GP Lead:

Site/Practice:

Date signed:

The original must be filed in the health professional's personal file and a copy held by their manager or employer for the purposes of ensuring practice occurs only in accordance with the PGD and is only undertaken by approved practitioners.

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