University Hospitals of Derby and Burton NHS Foundation Trust

Written instruction for Occupational Health Services

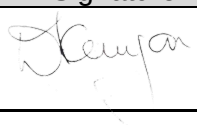
Registered Nurses ONLY

COMBINED LOW-DOSE DIPHTHERIA, TETANUS, AND INACTIVATED POLIO VACCINE (Td/IPV - REVAXIS) Vaccine

Documentation details

Reference no:	UHDB087
Version no:	V1.0
Valid from:	27/04/2021
Review date:	26/01/2024
Expiry date:	26/04/2024

Organisation name:	University Hospitals of Derby & Burton NHS Foundation Trust All UHDB sites plus any external sites where UHDB OH deliver their services.
Review date	3 years from approval
Details of local ratifying committee/governance approval or similar as appropriate:	In addition to the physician in occupational health services, this written instruction is to be approved by a chief pharmacist (or nominated deputy) and senior OH nurse (or nominated deputy).

Pharmacist designation:		
Name	Signature	Date
James Hooley		27/04/2021
Nursing designation:	Nurse consultant	88E1197E
Name	Signature	Date
Lucy Kenyon		1/5/2021

Name and signature of the registered doctor authorising registered nurses, who declare themselves (in Section 3) to have met the training and competency requirements defined in this written instruction, to operate under this written instruction on behalf of the named organisation.

Name	GMC Registration Number	Job Title	Signature	Date
Ilias Macheridis	6138922	AdvDipOccMed DDAM, MScPH OHP		28.04.2021

Local enquiries regarding the use of this Written Instruction may be directed to UHDB.PGDgovernance@nhs.net

Section 5 provides a registered health professional authorisation sheet. Individual professionals must have signed this declaration prior to practising under this Written Instruction.

Change history

Version number	Change details	Date
1	Changed from PGD to Written Instructions	21/04/2021

28.04.2021

1. Training requirements

Qualifications and professional registration	Nurses currently registered with the Nursing and Midwifery Council (NMC).
Training and competency	The registered nurse must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC) and online Immunisation Against Infectious Disease ('The Green Book'). The registered nurse must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD). The registered nurse should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Successful completion of the Trust written Drug Assessment & any essential to role Medicines Management/Safety training. The registered nurse must be competent: • to undertake immunisation and to discuss issues related to immunisation • in the handling and storage of vaccines, and management of the 'cold chain' • in the recognition and management of anaphylaxis • must have access to the Written Instructions and any associated online resources. Annual attendance at Trust BLS training including anaphylaxis and AED training. Annual immunisation and vaccination update training by face to face taught sessions or e-learning via link below: https://www.e-lfh.org.uk/programmes/immunisation/
Competency assessment	Registered nurses operating under this written instruction are personally responsible for ensuring they remain up to date with the use of the products included. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the Written Instruction and further training provided as required.

2. Clinical condition or situation to which this Written Instruction applies:

Clinical condition or situation to which this written instruction applies	Adults 16 years of age and above needing protection for diphtheria for occupational purposes – staff within pathology particularly microbiology and mortuary who may be exposed to diphtheria in the course of their work and clinical infectious disease units. *Note: Includes staff of the authorising organisation or staff members of another organisation the authorising organisation is commissioned to provide this vaccination service to.*
Criteria for inclusion	Pathology and clinical infectious disease workers handling specimens, which may contain diphtheria organisms. • UHDB HCWs / non-clinical workers as detailed above • Individuals needing protection for occupational purposes who are working in organisations where Occupational Health are contracted / commissioned to provide a service.
Criteria for exclusion	• Consent not gained (for further information on consent see DH Reference guide to consent for examination or treatment) • Have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus or inactivated polio containing vaccine (including conjugate vaccines containing diphtheria or tetanus toxoid) • Have had a confirmed anaphylactic reaction to any components of the vaccine (including trace components from the manufacturing process which may include neomycin, streptomycin or polymixin B) - see Summary of Product Characteristics • Suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • Non - occupational purposes including travel or following tetanus prone wound injury.
Cautions including any relevant action to be taken	If an individual is acutely unwell, immunisation should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. Previous severe reaction to vaccination. Clarify nature of reaction and seek further advice. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids. Td/IPV can be given to pregnant women when protection is required, however vaccination is not recommended unless the risk of diphtheria infection is high. Specialist advice should be sought before vaccinating. However, pregnant women from week 16 of pregnancy onwards should instead be protected by the administration of the routinely indicated dTaP/IPV - Pertussis containing vaccine (see alternative Written instruction for that product and/or refer to maternity services PGD and consider if this has been or could be offered within antenatal service).

	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. 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 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.
Action to be taken if the client is excluded	• In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed. • Document the reason for exclusion and any action taken in the individual's Occupational Health records. • Individuals excluded for health reasons or who have had a confirmed anaphylactic reaction to a previous dose of Diphtheria vaccine or any components of the vaccine should be referred to a Senior Clinician for specialist advice and appropriate management. • Inform manager in writing if the individual's occupation places them at risk through exposure.
Action to be taken if the client or carer declines treatment	• Document advice given and the decision reached • Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. • Inform manager in writing if the individual's occupation places them at risk through exposure. • Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.
Arrangements for referral for medical advice	Inform and seek advice from the Senior Occupational Health Clinician as appropriate. In case of allergies or specialist treatment refer individual to their GP or Specialist Clinician.

3. Description of treatment

Name, strength & formulation of drug	• Adsorbed diphtheria (low dose), tetanus, and inactivated poliomyelitis vaccine (Td/IPV): • Revaxis® , suspension for injection in a pre-filled syringe
Legal category	POM - Prescription only medicine
Route / method of administration	• Administer by intramuscular injection into the deltoid region of the upper arm. • For individuals with a bleeding disorder, vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. • 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 in different arms. The site at which each was given should be noted in the individual's records. • 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.
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 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 stabilised or the expected course of the condition becomes clear in accordance with the recommendations in Chapter 15 and Chapter 30 of 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 drug is recommended off-label consider, as part of the consent process, informing the individual that the drug is being

	offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	Single 0.5ml dose per administration The immunisation history of all individuals exposed to diphtheria should be established before commencing vaccinations to ensure they are up to date with the recommended UK immunisation programmes. Unimmunised individuals should receive a primary course, consisting of three doses at monthly intervals; with an antibody test 3 months post vaccine to confirm protective immunity. The cut-off level for diphtheria immunity is 0.01 iu/ml for microbiology / mortuary staff. A five year booster is recommended in these individuals and then reinforcing boosters as per other laboratory workers as below. Where a primary course is interrupted it should be resumed but not repeated. If an initial booster is given, an antibody test should be done 3 months post vaccine to confirm protective immunity. Reinforcing booster dose will be due 10 years after the final dose for laboratory workers at continued risk of exposure. In order to minimise the risk of adverse events, Revaxis should not be administered to individuals who completed a primary vaccination course or received a booster of a vaccine containing diphtheria or tetanus toxoids within the previous five years.
Obtaining supplies	Vaccine supplies will be ordered from Pharmacy Stores using the stock list protocol set up by pharmacy
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Store at between +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.
Drug interactions	The following interactions have been identified and should be considered where it is known a client is on the following medicines: • Immunological response may be diminished in those receiving immunosuppressive treatment. However vaccination is recommended even if the antibody response may be limited. • May be given at the same time as other vaccines.

	Please refer to the relevant SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	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
Management of and reporting procedure for adverse reactions	• Healthcare professionals and clients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual occupational health record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use. • If anaphylaxis management may be required ensure immediate access to blue Anaphylaxis box for treatment of Anaphylaxis (Follow algorithm in Anaphylaxis box).
Written information to be given to client or carer	Offer marketing authorisation holder's patient information leaflet (PIL) if available in the pack and any relevant OH leaflet.
Client advice / follow up treatment	Inform the individual of possible side effects and their management. The individual should be advised to seek medical advice in the event of an adverse reaction. When applicable, advise the individual when the subsequent dose is due. Individuals should be informed about the importance of completing the vaccination course. When administration is postponed advise the individual when to return for vaccination.
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.

Records	Record in line with local procedure: • that valid informed consent was given • name of individual, address, date of birth • name of registered nurse operating under this instruction • name and brand of product • date of administration • dose, form and route of administration • quantity administered • batch number and expiry date • anatomical site of administration • when next dose is due (if applicable) • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • Clarify it was administered under 'written instruction' Records should be signed and dated (or password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous and recorded on the occupational health database.

4. Key references

Key references	• Summary of product characteristic for Revaxis® , Sanofi Pasteur. Last updated 30 July 2020. https://www.medicines.org.uk/emc/product/5581 • Electronic BNF https://bnf.nice.org.uk/ • Immunisation Against Infectious Disease: The Green Book Chapter 12, updated 20 March 2013 https://www.gov.uk/government/publications/immunisation-of-healthcare-and-laboratory-staff-the-green-book-chapter-12 • PHE – Td/IPV Vaccine – PGD template https://www.england.nhs.uk/south-east/wp-content/uploads/sites/45/2019/11/PHE-PGD-GW-774-TdIPV-2019-09-12-v03.00.pdf • Immunisation Against Infectious Disease: The Green Book Chapter 15, updated 19 April 2013 https://www.gov.uk/government/publications/diphtheria-the-green-book-chapter-15 • 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 • PHE Vaccine Incident Guidance

	https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

5. Practitioner authorisation sheet – COMBINED LOW-DOSE DIPHTHERIA, TETANUS, AND INACTIVATED POLIO VACCINE (Td/IPV - REVAXIS) Vaccine

Details of Registered Nurses working for University Hospitals of Derby & Burton NHS Foundation Trust who have completed the required training and been assessed as competent (as detailed in Section 2 and confirmed by line manager/clinical supervisor signing below) who are authorised and willing to administer the vaccine in accordance with this written instruction as part of the named organisation's occupational health scheme, which may include peer to peer immunisation:

Name	Profession and Professional Registration Number	Signature	Date	Clinical Supervisor/Line manager name	Clinical supervisor/line manager signature	Date