University Hospitals of Derby and Burton NHS Foundation Trust

Written instruction for Occupational Health Services

Registered Nurses ONLY

Hepatitis A Vaccine

Documentation details

Reference no:	UHDB083
Version no:	V1.1
Valid from:	15/02/2022
Review date:	15/08/2024
Expiry date:	14/02/2025

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:	Medicines Safety Officer	
Name	Signature	Date
James Hooley	Signed copy held in Pharmacy	15/02/2022
Nursing designation:	Occupational Health Nurse, Infection Control Lead	
Name	Signature	Date
Fiona Calladine	Signed copy held in Pharmacy	10/02/2022

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
Fauzia Begum	7458082	OH Physician	Signed copy held in Pharmacy	15/02/2022

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	16/04/2021
1.1	Added VAQTA brand	16/12/2021

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 needing protection for Hepatitis A for occupational purposes in accordance with the Green Book – this includes those who frequently have contact with untreated sewage, pathology workers regularly handling these organisms, residential institutions / day centres / food packaging/handling. *Note: Staff refers to 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	Adults (16 years and over; 18 or over for VAQTA brand) meeting the above criteria for occupational protection. • UHDB HCWs as detailed above • Individuals 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) • Previous local or systemic reactions to the vaccine • Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics • Hypersensitivity to neomycin (all brands) • Hypersensitivity to formaldehyde (VAQTA brand only) • Previous Hepatitis A infection confirmed by blood test. • Confirmed anaphylactic reaction to a previous dose of a hepatitis A-containing vaccine • Non - occupational purposes including travel or risk of exposure due to lifestyle • Suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • Avoid VAQTA brand in Latex sensitive individuals
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. Hepatitis A-containing vaccines may be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids. 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. Allergy to latex. Check manufacturer's details if product or packaging contains latex (see exclusions for VAQTA).
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 hepatitis A 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	Hepatitis A (inactivated) vaccine (adsorbed), either: • **Havrix® Monodose®** vaccine, hepatitis A virus 1440 ELISA units in a pre-filled syringe or vial • **AVAXIM®**, hepatitis A virus, (GBM strain) 160 U, suspension for injection in a pre-filled syringe • **VAQTA® Adult** 1.0ml (50 U) pre-filled syringe or vial
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 suspension for injection may sediment during storage. Shake the vaccine well before administration to obtain a slightly opaque, white suspension. • The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.
Indicate any off-label use (if relevant)	Administration of Havrix® Monodose by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration but is in line with advice in Chapter 4 and Chapter 17 of 'The Green Book'. Licensed administration of another brand of hepatitis vaccine where available may be considered as an alternative. 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	**Dosage** Avaxim = 0.5ml pre filled syringe. Havrix Monodose = 1ml pre filled syringe. VAQTA® Adult = 1ml (50 U) pre-filled syringe or vial

	Frequency Primary immunisation – consists of a single dose of vaccine which lasts for at least one year. Reinforcing dose - a booster dose of Hepatitis A vaccine should be given at six to 12 months after the initial dose. This results in a substantial increase in the antibody titre and will give immunity beyond ten years. Until further evidence is available on persistence of protective immunity, a further booster at 25 years is indicated for those at ongoing risk. If a course of vaccination is interrupted (or not completed on time) for any reason, then resume the vaccination schedule at the point it was left off and complete the course of vaccinations as if there had been no break. **DO NOT** start the schedule again.
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. Stability data indicate that Havrix is stable at temperatures up to 25°C for 3 days. These data are intended to guide healthcare professionals in case of temporary temperature excursion only. 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	Adverse reactions to hepatitis A vaccines are usually mild and confined to the first few days after immunisation. The most common reactions are mild, transient soreness, erythema and induration at the injection site. A small, painless nodule may form at the injection

	site; this usually disappears and is of no consequence. Other commonly reported reactions to hepatitis A vaccination include general symptoms such as fever, malaise, fatigue, irritability, drowsiness, headache, myalgia, arthralgia and gastrointestinal symptoms including nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. Hypersensitivity reactions and anaphylaxis can occur but are very rare. 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. When administration is postponed advise the individual when to return for vaccination.
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) injection and access to a telephone at the time of vaccination. There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since hepatitis A vaccine is an inactivated vaccine, the risks to the foetus are negligible and it should be given where there is a definite risk of infection.
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 AVAXIM®, Sanofi Pasteur. Last updated 01 October 2019. https://www.medicines.org.uk/emc/product/1394 • Summary of Product Characteristic for Havrix® Monodose®, GlaxoSmithKline UK. Last updated 24/11/2020 *https://www.medicines.org.uk/emc/product/1158* Summary of Product Characteristics for VAQTA® , Merck Sharp & Dohme UK Ltd. Last updated 11/12/21. https://www.medicines.org.uk/emc/product/1396/smpc • Electronic BNF https://bnf.nice.org.uk/ • PHE – Hepatitis A Vaccine – PGD template https://www.gov.uk/government/publications/hepatitis-a-vaccine-patient-group-direction-pgd-template • Immunisation Against Infectious Disease: The Green Book Chapter 17, updated December 2013 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/263309/Green_Book_Chapter_17_v2_0.pdf • 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 – Hepatitis A 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