PGD5517

South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

Patient Group Direction

Administration of Hepatitis A & B Vaccine

By Registered Nurses and Midwives in Integrated Sexual Health employed by South Staffordshire & Shropshire Healthcare Foundation NHS Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:			
Position of Signatory	**Name**	**Signed**	**Date**
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing & Chief Operating Officer	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust, are authorised to administer Hepatitis A & B vaccines to patients in Integrated Sexual Health, under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from 1st October 2017.
Review date: August 2019. Expires on 31st October 2019.

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire HealthCare NHS Foundation Trust are authorised to administer Hepatitis A & B vaccine as specified under this Patient Group direction following demonstration of the competencies below;

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training on an annual basis in order to carry out clinical assessments of service users leading to injection being given according to the indications listed in the PGD

2. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis

3. Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan

4. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)

5. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines

6. All registered nurses details and signature must be entered on the PGD

7. Following administration a record of the site, date, stage and batch number of the vaccine should be recorded in the service users records, and and within the As Required section of the medicine card, with PGD Number being inserted in place of prescriber's instructions

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (http://emc.medicines.org.uk)

Supply/Administration of	Hepatitis A and Hepatitis B Vaccine
Legal Classification	POM
Black Triangle?	No
Type	Inactivated hepatitis A virus 720 ELISA units and recombinant (DNA) hepatitis B surface antigen 20mcg/ml adsorbed onto aluminium phosphate. Twinrix Adult – 1ml Twinrix Paediatric – 0.5ml
Storage	$+2^{O}C$ to $+8^{0}C$. Do not freeze. Protect from light.
Condition to be treated	Immunisation against hepatitis A and hepatitis B infection in service users at risk.
Inclusion Criteria	▪ Individuals who are at risk due to their sexual behaviour ▪ Parenteral drug abusers
Exclusion Criteria	▪ Febrile illness. ▪ Previous Hepatitis A infection confirmed by blood test. ▪ Allergy to any component of vaccine. ▪ Pregnancy & lactation ▪ Post-exposure prophylaxis following percutaneous (needle-stick), ocular or mucous membrane exposure to hepatitis B virus ▪ Haemophiliacs ▪ Chronic liver disease ▪ Pregnancy & lactation ▪ Dialysed or immunocompromised
Action if excluded or patient declines	Effect in pregnancy/breast feeding not assessed – utilisation during pregnancy requires that the potential benefit justifies the potential risk to foetus, and independent prescriber decision required.
Reasons for seeking further advice from doctor	• Pregnancy & lactation • Haemophiliacs and service users with chronic liver disease should be checked for previous exposure before immunisation.
Administration Route	Intramuscular injection. The deltoid region is the preferred site. The anterolateral thigh for infants. Not to be injected in the buttock.

Dose	16 years and over - 1.0ml 1 year up to and including 15 years – 0.5ml
Administration Schedule	**Adult 16 Years and Above 20 micrograms in 1ml** **Standard Schedule** Immediate 1st injection, 2nd dose 1 month after first dose, 3rd dose 2 months after first dose, followed by a fourth dose 12 months after first dose. Total dose number: 4**.** **Rapid Induction** Immediate 1st injection, 2nd in seven days, 3rd twenty-one days after the first injection, followed by a booster at 12 months. Total dose number: 4. **Paediatric 13 – 15 Years 10 micrograms in 0.5ml** Immediate 1st injection, 2nd dose 1 month after first dose, 3rd dose 2 months after first dose, followed by a fourth dose 12 months after first dose. Total dose number: 4**.** **Booster dose as clinically indicated** **Refer to local Sexual Health departmental guidelines** If patients do not attend as the planned schedule, eg, they attend 6 weeks instead of 4 weeks for the next dose, the schedule can still continue and does not have to be restarted. In situations where a booster dose of both hepatitis A and hepatitis B are desired, Twinrix or the monovalent vaccines can be given.
Warnings/Adverse Reactions	Vaccine may not be effective in 100% of service users It is possible that subjects may be in the incubation period of hepatitis A or hepatitis B infection at the time of vaccination. The vaccine may not prevent infection in such cases. Does not provide immediate protection; antibody induction may take 2-4 weeks The most common reactions, occurring in up-to half of the vaccines, are mild transient local soreness, erythema and induration at the injection site.

	Local swelling at the injection site and angioedema have been reported rarely. Fever, malaise, nausea, dizziness. Early onset allergic-type reactions have been reported rarely.
Advice/Management of Adverse Reactions & Follow-up Action	The vaccine has not been tested in service users with impaired immunity. In haemodialysis service users and persons with an impaired immune system adequate antibody titres may not be obtained after the primary immunisation course and such service users may require additional doses. Thiomersal is used in the manufacturing process and residues are present in the final product. Therefore sensitisation reactions may occur. Side Effects are usually mild. **Anaphylaxis Emergency Treatment** Have Adrenaline (Epinephrine) 1:1000 ready for use in case of anaphylaxis. See PGD for the Administration of Adrenaline (Epinephrine) 1:1000. Advice about hygiene Advise patient when next immunisation due and if concerned about a reaction to seek advice from nurse or doctor If an adverse reaction does occur then: 1. Inform the patient's GP as soon as possible. 2. Report the reaction to the CSM using the yellow card system
Records	**The following should be recorded in the patient's notes:** • Name and brand • Batch number and expiry date • Dose given • Time given • Route and site of administration • When next dose due • Date • Signature <u>and</u> the administration also recorded in the medicine card/electronic prescribing & medicines administration record, with the PGD Number

	recorded as authorisation.