Patient Group Direction
for *Pharmacists and Nurses to*
administer Hepatitis A vaccine for Travel
in adults and children aged One year and over

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*** If this PGD is past its review date then the content will remain valid until such time as the PGD review is complete and the new issue published**

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Developed by	Designation	Signature	Date
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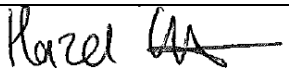
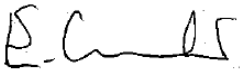
Hazel Close	Lead Pharmacist Public Health NHS Fife		21.02.22

This Patient group Direction has been approved on behalf of NHS Fife by:

Name	Designation	Signature	Date
Nicola Robertson	Associate Director of Nursing NHS Fife		10.03.22
Dr Esther Curnock	Deputy Director of Public Health Consultant in Public Health Medicine, NHS Fife		16.03.22
Fiona Forrest	Deputy Director of Pharmacy & Medicines NHS Fife		11.03.22

1. Clinical condition to which the patient group direction applies

Indication	Active immunisation of individuals who are deemed to be at risk from exposure to hepatitis A virus.
Inclusion criteria	• Valid consent to treatment according to NHS Fife policy Adults and children over 1 year old who: • intend to travel to or reside in countries where hepatitis A vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX www.travax.nhs.uk/destinations/ • the risk of exposure should be determined after careful risk assessment of an individual's itinerary, duration of stay, planned activities and medical history.
Exclusion criteria	• No valid consent to treatment according to NHS Fife policy Individuals who: • are under one year of age • have had a confirmed anaphylactic reaction to a previous dose of any hepatitis A containing vaccine or to any components of the vaccine, these may include neomycin and/or formaldehyde (refer to relevant SPC) • have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free • are solely at occupational risk of hepatitis A exposure, should be referred to their employer's occupational health provider for vaccination • previous confirmed hepatitis A infection • suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions / Circumstances when further advice should be sought from a doctor	• It is the responsibility of the designated, authorised staff using this PGD to ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt, advice should be sought and recorded before the drug is administered / supplied. • The Green Book advises there are very few individuals who cannot receive hepatitis A containing vaccines. When there is doubt, appropriate advice should be sought from the lead clinician rather than withholding the vaccine. • Individuals with immunosuppression and HIV infection can be given hepatitis A containing vaccines although seroconversion rates and antibody titre may be lower. Specialist advice may be required. • 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.
Action if excluded	• Do not use the PGD • The patient must be referred to an authorised prescriber • The reason for referral should be documented Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account. Refer to the lead clinician. Document the reason for exclusion and any action taken in accordance with local procedures. Advise the individual/parent/carer of preventative measures to reduce exposure to hepatitis A including careful attention to food and water hygiene and scrupulous hand washing. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Individuals who have had a confirmed anaphylactic reaction to a previous dose of a hepatitis A containing vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management.
Action if patient declines treatment	• The patient must be referred to an authorised prescriber • The reason for refusal should be documented • Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease. Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine. • Advise the individual/parent/carer of preventative measures to reduce exposure to hepatitis A including careful attention to food and water hygiene and scrupulous hand washing. • Document advice given and decision reached. Inform or refer to the lead clinician in charge.

2. Medication details

Name strength & formulation of drug	**Adults** • Vaqta Adult® 50 antigen units/1ml • Avaxim® 160 antigen units/0.5ml • Havrix Monodose® 1440 ELISA units/1ml per dose **Children** • Vaqta Paediatric 25 antigen units/0.5ml • Havrix Junior Monodose® 720 ELISA units/0.5ml per dose

Route of administration	Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm. In small infants the anterolateral thigh may be used. 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 must be reconstituted in accordance with the manufacturer's instructions prior to administration. 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.
Dosage	

Vaccine product	Ages	Dose	Volume
ADULTS			
Vaqta Adult®	18 years or over	50 units	1.0ml
Avaxim®	16 years or over	160 antigen units	0.5ml
Havrix Monodose®	16 years or over	1440 ELISA units	1.0ml
CHILDREN			
Vaqta Paediatric®	One to 17 years	25 units	0.5ml
Havrix Junior Monodose®	One to 15 years	720 ELISA units	0.5ml

Vaccines can be used interchangeably.

Please note in clinical settings where there is more than one option for vaccination available, the following order of preference should be used.

Adults
1. VAQTA® Adult
2. Avaxim®
3. Havrix® Monodose®

Children

	1. VAQTA® Paediatric 2. Havrix® Junior Monodose®
Frequency of administration	**Primary immunisation:** single dose (see table above). Vaccination should ideally occur at least 2 weeks prior to possible exposure to infection with hepatitis A. For travellers, vaccine should preferably be given at least two weeks before departure, but can be given up to the day of departure. **Reinforcing Immunisation:** For those who require prolonged or subsequent protection against infection caused by hepatitis A virus, a reinforcing booster dose of a hepatitis A containing vaccine should ideally be given 6-12 months after the first dose. If the booster dose is delayed beyond 12 months, the course does NOT need to be restarted as studies have shown boosting can occur even when the second dose is delayed for several years. Hepatitis A containing vaccines may be used interchangeably, as appropriate, to complete a course. Until further evidence is available on persistence of protective immunity, a further booster at 25 years is indicated for those at ongoing risk of hepatitis A.
Duration of treatment including maximum/ minimum period if applicable	As above
Quantity to be supplied	One dose per occasion
Patient advice verbal and written	Written information to be given to individuals: • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. Individual advice / follow up treatment: • Inform the individual/carer of possible side effects and their management • Explain that to give long-lasting immunity to hepatitis A, dosing requires two injections at least six months apart • Advise the individual/parent/carer of preventative measures to reduce exposure to hepatitis A including careful attention to food and water hygiene and scrupulous hand washing • The individual/carer should be advised that hepatitis A vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis B, C and hepatitis E viruses. • The individual should be advised to seek medical advice in the event of a severe adverse reaction • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk/

Legal category	Prescription Only Medicine (POM)
Use outwith SPC	Administration of Havrix® Monodose or Havrix® Junior Monodose® by deep subcutaneous injection to patients 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. Where a vaccine is recommended off-label consider, as part of the consent process, inform the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions the HPS Guidance for Vaccine Storage and Handling must be followed (link). If a vaccine or cold chain incident occurs the Health Protection Scotland Vaccine Incident Guidance should be followed vaccine-incident-guidance-actions-to-take-in-response-to-vaccine-errors and advice must be sought from the Pharmacy Governance team by calling 01383 565347. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Storage requirements	• Ensure within expiry date • Vaccine should be stored at a temperature of +2° to +8°C. • Store in the original packaging to protect from light. • Do not freeze. • Contact Pharmacy for advice if stored out with +2°C to +8°C • There may be circumstances when vaccines stored out with the recommended storage temperatures of +2 to +8°C can be administered providing the product has been confirmed as suitable for use by the manufacturers and Pharmacy • the HPS Guidance for Vaccine Storage and Handling must be followed (link) see above.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.
Black Triangle Drug ▲	No
Additional information	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. Immunological response may be diminished in those receiving immunosuppressive treatment. There is no evidence of risk from vaccinating pregnant women, or those who are breast-feeding, with inactivated virus or bacterial vaccines or toxoids. Vaccination should be considered when the risk of infection is high and benefits are considered to outweigh the risks. 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 was given should be noted in the individual's records.
Identification and management of adverse reactions	• For full details/information on possible side effects, refer to the marketing authorisation holder's SPC. • 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. • As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. • In the event of severe adverse reaction individual should be advised to seek medical advice. • Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed. • All suspected serious reactions should be reported directly to the MHRA/Commission on Human Medicines through the Yellow Card scheme and recorded in the patient's medical notes. Reports should be made online at https://yellowcard.mhra.gov.uk
Monitoring if required	Following immunisation, patients remain under observation in line with NHS Fife policy.
Follow up – appointment with or notification to GP required?	As above
Additional facilities/ supplies required	• Immediate access to anaphylaxis medication as appropriate to current NHS Fife procedure for the Management of Anaphylaxis. • Immediate telephone access to GP • Access to a BNF • NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) should be followed • Adhere to hand decontamination policy
Disposal	As per SSUMPP

3. Staff characteristics

Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines:

	• pharmacists currently registered with the General Pharmaceutical Council (GPhC) • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
Specialist competencies or qualifications	• *Registered Pharmacist or Nurse* who is competent to undertake supply and administration of medicines under Patient Group Directions. • Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the PGD, using NHS Fife approved diagnostic algorithm • Has undertaken NHS Fife approved anaphylaxis management training. • Has undertaken NHS Fife training in *paediatric and adult basic* life support • It is essential that the NHS Fife approved PGD e-learning programme is accessed and completed
Continued training requirements	• Maintain own professional level of competence and knowledge in this area • Keep up-to-date with information on contraindications, cautions and interactions for Havrix Monodose®,Havrix Junior Monodose®, Avaxim®, Vaqta Adult®, Vaqta Paediatric from the BNF, SPC and PIL and refer to a doctor if necessary • Annual update of anaphylaxis management according to NHS Fife Policy • Annual update of training in paediatric and adult basic life support • A 2 yearly update of the PGD e-learning programme is essential

4. Referral arrangements/Audit trail

Arrangements for referral to medical advice	• The patient may be referred to a doctor at any stage, if this is necessary, in the professional opinion of the *healthcare professional*. • Patients should be referred to the doctor if treatment proves to be ineffective in relieving the symptoms
Records/Audit trail	• Enter in record - date - name of patient - Date of birth/ CHI no. - name of medicine - batch number and manufacturer - expiry date - dose/volume - quantity administered - route and site of administration - name of clinician providing treatment - signature / individual log-on details of clinician providing treatment • Record on appropriate form. • Record medical history taken, diagnosis and the advice given to the patient/carer
References/ Resources & comments	• BNF / BNFc latest edition available at www.medicinescomplete.com • NHS Fife Consent Policy • NHS Fife Procedure for the Management of Anaphylaxis • NHS Fife Resuscitation Guidelines

	• NMC/RPS Administration of Medicines Guidance Jan 2019 • NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) • Summary of Product Characteristics available at www.medicines.org.uk • Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Immunisation against Infectious Disease [Green Book] chapter 17 https://www.gov.uk/government/publications/hepatitis-a-the-green-book-chapter-17 • Current edition of British National Formulary. • Marketing authorisation holder's Summary of Product Characteristics. • Professional Guidance on the Administration of Medicines in Healthcare Settings 2019 https://www.rpharms.com/Portals/0/RPS document library/Open access/Professional standards/SSHM Admin/Admin Meds prof guidance.pdf/ver=2019-01-23-145026-567 • Professional Guidance on the Safe and Secure Handling of Medicines https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines • PHE Hepatitis A Vaccine Patient Group Direction (PGD) https://www.england.nhs.uk/south-east/wp-content/uploads/sites/45/2019/11/PHE-PGD-GW-772-HepA-2019-09-12-v02.00.pdf • HPS Guidance for Vaccine Storage and Handling (link). • HPS Vaccine Incident Guidance vaccine-incident-guidance-actions-to-take-in-response-to-vaccine-errors • NHSGGC Hepatitis A vaccine PGD ref no: 2019/1986

This Patient Group Direction has been assessed for Equality and Diversity Impact

5. Management and monitoring of patient group direction

Patient Group Direction
for *Pharmacists and Nurses to*
administer **Hepatitis A vaccine** for Travel
in adults and children aged One year and over

This patient group direction is to be read, agreed to, and signed by all *healthcare professionals* it applies to. One signed copy is to be given to each clinician with the original being kept on file by the line manager. One signed copy should be forwarded to the appropriate lead nurse / lead clinician where applicable.

Pharmacist/Nurse Agreement

I _____, confirm that I have read and understood the above Patient Group Direction. I confirm that I have the necessary professional registration, competence, and knowledge to apply the Patient Group Direction. I will ensure my competence is updated as necessary. I will have ready access to a copy of the Patient Group Direction in the clinical setting in which supply or administration of the medicine will take place.

I understand that it is the responsibility of the healthcare professional to act in accordance with the GPhC/ NMC Guidelines for Professional Practice and Guidelines for the Administration (or Supply) of Medicines and to keep an up to date record of training and competency.

Name of clinician----------

Professional Category----------

Registration No.----------

Is authorised to give **Havrix Monodose®, Havrix Junior Monodose®, Avaxim®, Vaqta Adult®, Vaqta® Paediatric** under this patient group direction

Place of Work----------

Signature of clinician----------

Date----------

Authorised by: **(not required for pharmacists)**

Name of authorising clinician/manager----------

Signature----------

Date----------

Pharmacists send signed copy of this page to fife.pgd@nhs.scot

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