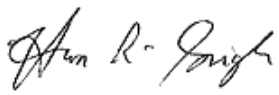
Patient Group Direction (PGD) for the Administration of

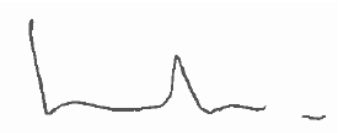
HEPATITIS A VACCINES

by Registered Professionals to Individuals Accessing NHS Services in Cumbria and North East Sub Region (NHS England North)

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

Direction Number: - **NECSAT 2017/001**
Valid from: 1st March 2017
Review date: 1st December 2018
Expiry date: 31st March 2019

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author) (North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		17/01/17
Transforming Care Quality Manager (NHS England, Cumbria and North East)	**Kathryn Dimmick** *(Senior Nurse)*		21/02/17
Medicines Optimisation Pharmacist (North of England Commissioning Support)	**Marie Thompkins** *(Senior Pharmacist)*		22/01/17
Assistant Medical Director (NHS England, Cumbria and North East)	**Dr James Gossow** *(Senior Doctor)*		27/02/17

This PGD has been approved for use in Cumbria and North East Sub Region (NHS England) by:			
Title	Name	Signature	Date
Interim Medical Director (NHS England Cumbria and North East)	**Dr Jonathan Slade** *(Governance Authorisation)*		27/02/17

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

Immunisation against Hepatitis A infection in adults and children aged 1 year or over.

Objectives of care

- To prevent infectious disease and promote health. To reduce morbidity & mortality and to eradicate disease.

Inclusion criteria (as per Public Health England (PHE) Green Book Guidance

Those adults & children from 1year of age, who are in one of the groups recommended to receive pre-exposure vaccination against Hepatitis A infection, (see the Green Book Chapter 17) and where valid consent has been given/ best interest decision is in place. These are as follows:

- Travel to moderate or high risk area and vaccination is recommended.
- **Previously unvaccinated** individuals who have been in close contact with a confirmed case of Hepatitis A (with onset of jaundice/disease within last seven days in the primary case).
- Patients who have chronic liver disease or for individuals infected with Hepatitis B or C.
- Patient with haemophilia who receive plasma-derived clotting factors.
- Those who are at risk due to their sexual behaviour and men who have sex with men.
- Injecting drug users.
- Users of day care facilities or residential homes for those with severe learning difficulties.

Exclusion criteria

General exclusions *(Refer to current Summary of Product Characteristics (SPC) and latest BNF (Appendix 1) for full list of details)***: -**

- No valid consent /best interest decision in place;
- Children under 12 months of age.
- Patient is acutely unwell – (postpone vaccination until recovered. Minor illnesses without fever or systemic upset are not reasons to postpone immunisation).
- Have a confirmed anaphylactic reaction to any component, ingredient or excipient of the vaccine. Practitioners must check the SPC.
- Have a confirmed anaphylactic reaction to a previous dose of a Hepatitis A containing vaccine.
- Severe hypersensitivity to any ingredient or component of the vaccine(s) – **(please also refer to precautions section).**

Specific exclusions:

- ***Avaxim***® (confirmed systemic hypersensitivity to neomycin)

  VAQTA® ***Adult and VAQTA***® ***Paediatric***: - (confirmed hypersensitivity to neomycin & formaldehyde)

  Havrix® ***Monodose***® : - (confirmed hypersensitivity to neomycin)

  Havrix® ***Junior Monodose***® : - (confirmed hypersensitivity to neomycin)

Refer to current Summary of Product Characteristics (SPC) / Green Book (current on-line version)/ latest BNF for full list of details

Precautions

- **Hypersensitivity reactions to previous dose of vaccine or component of vaccine:**
  - NB. "Local adverse reactions that generally start within a few hours of the injection are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens."
- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of a vaccine. Immediate access to epinephrine (adrenaline) 1 in 1000 injection. Syringes and needles of suitable size and capacity for dose should be available.
- **When two or more injections need to be administered at the same time**, they should be given at separate sites, preferably in a different limb. If more than one injection is to be given in the same limb they should be administered at least 2.5cm apart.
- **Pregnancy and breast feeding:**
  - Hepatitis A containing vaccines can 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 vaccines or toxoids.
- **Individuals with immunosuppression and HIV infection** can be given the vaccination but sero-conversion and antibody titre may be low. Re-immunisation should be considered and specialist advice may be required.
- **Use caution when vaccinating latex-sensitive individuals** with VAQTA Adult or Paediatric vaccine since the syringe plunger stopper and tip cap contain dry natural latex rubber that may cause allergic reactions.

Action if excluded

- There are few individuals who cannot receive hepatitis A containing vaccines. **When there is doubt or reason for caution, discuss with or refer to clinician/doctor/local communicable disease specialist.**
- Provide advice in sanitary and food hygiene. / Ensure all actions/decisions are documented.
- The risk to the individual of not being immunised must be taken into account.
- If postponement due to acute illness, arrange a future date for immunisation.

Circumstances in which further advice should be sought from a doctor and/or specialist

- Patient meeting the exclusion criteria.
- Patient requires additional information in order to decide whether or not to have the vaccination
- A Best Interest decision is required for an individual who lacks mental capacity to consent. Seek support from lead clinician responsible for individuals care.

Action if vaccination refused

- Refusal should be accepted. Ensure patient/guardian/carer fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications If postponement due to acute illness, arrange a future date for immunisation
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate

Special Considerations / Additional Information

Vaccine	
Avaxim	• Protective levels of antibody may not be reached until 14 days after administration. • Shake before injection to obtain a slightly opaque , white suspension
Havrix Monodose, Havrix Junior Monodose	• Confers protection against Hepatitis A within 2 to 4 weeks. • Before use, shake vaccine well to obtain a slightly opaque white suspension.
VAQTA Adult VAQTA Paediatric	• A period of 2-4 weeks is required before antibody induction occurs. • Shake well immediately before withdrawal and use. Thorough agitation is necessary to maintain suspension of the vaccine

2. Description of treatment

Name, strength & formulation of drug

Avaxim® (Sanofi Pasteur MSD):	0.5ml	pre-filled syringe	(The vaccine is a cloudy and white suspension)
Havrix® Junior Monodose (GSK):	0.5ml	pre-filled syringe	(type I glass) with a plunger stopper (rubber butyl)
Havrix® Monodose (GSK):	1ml	pre-filled syringe	(type I glass) with a plunger stopper (rubber butyl)
		(Both Havrix vaccines are slightly opaque white suspensions)	
VAQTA® Paediatric (Sanofi Pasteur MSD):	0.5ml	vial or pre-filled syringe	(Vaccine is a slightly opaque white suspension)
VAQTA® Adult (Sanofi Pasteur MSD):	1ml	vial or pre-filled syringe	(Vaccine is a slightly opaque white suspension)

Legal Status:

POM –Prescription Only Medicines

Dosage /Dose range

Avaxim	16 years or over:	Dose: 0.5ml
Havrix Junior Monodose	1-15 years:	Dose: 0.5ml
Havrix Monodose	16 years or over:	Dose: 1ml
VAQTA Paediatric	1-17 years of age:	Dose: 0.5ml
VAQTA Adult	18 years of age or over:	Dose: 1ml

Route/Method

Intramuscular injection (IM) is the preferred route: -

- **Not** to be given intravenously.
- **Not** to be administered in the gluteal muscle or intradermally since this may result in lower immune response.
- Exceptionally, can be administered subcutaneously in patients with thrombocytopenia or bleeding disorders.
- Hepatitis A vaccines can be given at the same time as other vaccines, but at separate site, preferably in a different limb. If given in the same limb, they should be given at least 2.5cm apart.

(Please refer to the manufacturer's SPCs and on line version of the Green Book for detailed information).

Frequency of Administration

Vaccine	Age range	First (Primary) dose	Second (Booster) dose
Avaxim	16 years old or over	**0.5ml primary dose** (Ideally at least 2 weeks before potential exposure to Hepatitis A)	**0.5ml (6 - 12 months after 1st dose)** May be administered from 6 months and up to 36 months after primary dose if not given at the recommended interval.
Havrix Monodose	16 years or over	**1ml at elected time**	**1ml (6 - 12 months after 1st dose)** Booster may be delayed up to 3 years after the primary dose if not given at the recommended time interval.
Havrix Junior Monodose	1-15 years	**0.5ml at elected time**	**0.5ml (6 - 12 months after 1st dose)** Booster may be delayed up to 3 years after the primary dose if not given at the recommended time interval.
VAQTA Adult	18 years of age and older	**1ml at elected time** (Should be given at least 2, preferably 4, weeks prior to expected exposure to hepatitis A)	**1ml (6 - 18 months after 1st dose)**
VAQTA Paediatric	1 – 17 years of age	**0.5ml** at elected time (Should be given at least 2, preferably 4, weeks prior to expected exposure to hepatitis A)	**0.5ml (6 - 18 months after 1st dose)**

- For travellers, vaccine should preferably be given at least 2 weeks before departure, but can be given up to the day of departure. (Although antibodies may not be detectable for 12-15 days following administration of hepatitis A vaccine).
- Avaxim, Havrix Monodose and Havrix Junior Monodose vaccines can be used as a booster in subjects previously immunised with any inactivated hepatitis A vaccine.
- A booster dose of ***VAQTA Adult and VAQTA Paediatric*** may be given 6-12mths following the initial dose of another inactivated hepatitis A vaccine.

Maximum dose & number of treatments

- Primary course consists of 2 vaccinations usually 6-12 months apart.
- Completion of primary course in healthy individuals will provide protection for up to 25 years.

Follow up treatment

Follow current Green Book recommendations as applicable

- Booster: - at 25 years is indicated for those at on-going risk

3. Further Aspects of Treatment

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See manufacturers SPC for full details / current Green Book online Chapter 18

Potential Adverse Effects/ Reactions: - Usually transient and only last a few days after vaccination.

Please be aware of Resuscitation Council Guidelines (2015)

Very Common & Common reactions Include:	• Injection site reactions such as: mild & transient soreness; swelling, redness and pain at the injection site. (Local reactions within 48hrs after vaccination and persisting for 1-2 days). • Headache and mild fever. Decreased appetite (uncommon with VAQTA adult and paediatric).
Less common effects include: -	• Dizziness & vomiting. Myalgia (except in VAQTA paediatric. Common with Avaxim) • Malaise & nausea (VAQTA adult & paediatric only). • **Others include: -** Arthralgia, pruritis, somnolence, insomnia and occasionally generalised rashes.
Rare and very rare	• Anaphylactic and allergic reactions

This list is not exhaustive. Please also refer to current manufacturers SPC for details of all potential adverse reactions and on line version of the Green Book for detailed information.

Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- Advice on management including anaphylaxis: - Chapter 8 of the Green Book provides detailed advice on managing adverse drug reactions (ADRs) following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor/specialist as appropriate

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and the online Green Book - Chapter 9.

  See manufacturers SPC for details of all potential adverse reactions.

Advice to Patient / Carer (verbal or written)

- Explain protection level expected from vaccine.
- Provide a patient information leaflet and discuss as required. Provide advice in sanitary and food hygiene as appropriate.
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above and manufacturers SPC).
- Explain procedure for dealing with anaphylaxis /severe allergic reactions.
- Explain the "Out of Hours" procedure. Give date of next vaccine if applicable.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.
- Complete patient-held vaccination record (where applicable)

Arrangements for Referral to Medical Advice

- Doctor/specialist appointment as and when appropriate. Additional vaccine related advice may also be obtained from Nathnac (http://www.nathnac.org) and Travax (http://www.travax.nhs.uk) websites.

Records

In all cases manual records, computerised records and data collection should include: -

- Patient's name and date of birth;
- Reason vaccination required;
- Brand name, batch no. & expiry date of vaccine;
- Date of administration;
- Whom administered by and signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed; Support literature given (if applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.
- Any immunisation/vaccine related incident should be reported to Cumbria and North East Sub Region (NHS England North).
- Confirmation that consent has been obtained;
- Dose, site and route of injection;

Additional Facilities

- Access to updated online Green Book information; the latest SPC and BNF.
- Store in a clinical refrigerator (+2°C to +8°C) and original packaging. Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline as applicable)

References

- NICE Good Practice Guidance 02 : Patient Group Directions Aug 2013
- Public Health England: Immunisation Against Infectious Disease - The "Green Book" Chapter 17: Hepatitis A (December 2013). Accessed at https://www.gov.uk/government/publications/hepatitis-a-the-green-book-chapter-17 on 16th January 2017

  Nursing and Midwifery Council (NMC), 2007: Standards for Medicines Management.
- Nursing and Midwifery Council (NMC), 2007: Record Keeping Advice Sheet.
- NMC, 2008: Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- Resuscitation Council (UK), October 2015: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- Sanofi Pasteur MSD Ltd; Avaxim® vaccine - SPC, 02/03/2015 (accessed from Electronic Medicines Compendium on 16.01.17).
- Sanofi Pasteur MSD Ltd; Havrix Monodose® vaccine - SPC, 09-Dec-2016 (accessed from Electronic Medicines Compendium on 16.01.17).
- GlaxoSmithKline Ltd; Havrix Junior Monodose® vaccine - SPC, 09/12/2016 (accessed from Electronic Medicines Compendium on 16.01.17).
- Sanofi Pasteur MSD Ltd; Vaqta® Paediatric vaccine - SPC, 18-Aug-2015 (accessed from Electronic Medicines Compendium on 16.01.17).
- Sanofi Pasteur MSD Ltd; Vaqta® Adult vaccine - SPC, 18-Aug-2015 (accessed from Electronic Medicines Compendium on 16.01.17).

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists
State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.		

Qualifications required (professional registration applies to specific professions)

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council

Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the HPA National minimum standards in immunisation training 2005 either through training or professional competence ensuring that annual training is offered to all staff
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and *Immunisation Against Infectious Disease* (Green Book online version).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

Continued training requirements (applies to all staff)

- Annual attendance at an update on resuscitation skills and the management of anaphylaxis within the community/primary care **(mandatory).**
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation **(recommended).**
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Management & Monitoring of Patient Group Direction NECSAT 2017/001

The Administration of

HEPATITIS A VACCINES (Avaxim®, Havrix Junior Monodose®, Havrix Monodose®, VAQTA Adult and VAQTA Paediatric Injection®)

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:-_____

I have read and understood the Patient Group Direction.

HEPATITIS A VACCINES

I agree to administer Hepatitis A Vaccines only in accordance with this Patient Group Direction (NECSAT 2017/001)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

I agree that the above named healthcare professional is authorised to administer medicines in accordance with this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from: 1st March 2017	Review Date: - Dec. 2018	**Expiry Date: - 31st March 2019**

Management & Monitoring of Patient Group Direction NECSAT 2017/001

HEPATITIS A VACCINES

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

Hepatitis A Vaccines under the Patient Group Direction (NECSAT 2017/001)

PGD Valid from date: 1st March 2017 **PGD Expiry Date:** 31st March 2019

Healthcare Professional			**Authorised by:**		
Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

PGD Valid from: 1st March 2017	Review Date: - Dec. 2018	**Expiry Date: - 31st March, 2019**