

Medicines Management Team
Pharmacy and Medicines Directorate
Westholme
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Aberdeen
AB15 6LS

Date: 12th of July 2022
Our Ref: FA/PGD/HepA/MGPG1036/July22
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Dear Colleagues

This letter authorises the extended use of the following North of Scotland (NoS) Patient Group Direction (PGD) until 1st October 2022:

Patient Group Direction For The Administration Of Hepatitis A Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 1.1

This PGD is currently under review following the release of the Public Health Scotland PGD template on June 30th. This letter provides permission to continue using the PGD to a new expiry date of 1st October 2022, and should be kept with the PGD records and brought to the attention of the individual healthcare professionals who operate under the PGD currently.

If you have any queries regarding this please do not hesitate to contact Frances Adamson the Clinical Lead for NoS PGD working.


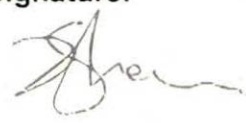
Yours sincerely

A handwritten signature in blue ink, appearing to read 'Lesley Coyle'.

Lesley Coyle
Chair of North of Scotland PGD Group

**Patient Group Direction For The Administration Of Hepatitis A
 Vaccine By Approved Healthcare Professionals Working Within NHS
 Grampian, Highland, Orkney, Shetland, Tayside and Western Isles**

Lead Author: Medicines Management Specialist Nurse NHS Grampian	Consultation Group: See relevant page in the PGD	Approver: NoS PGD Group Authorisation: NHS Grampian
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Signature: 		Signature: 
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NoS Identifier: NoS/PGD/HepA/ MGPG1036	Review Date: June 2021 Expiry Date: June 2022	Date Approved: June 2019
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NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed
Version 1.1 (Amended March 2021)

Revision History:

Reference and approval date of PGD that has been adapted or superseded	New PGD adapted from NHSG/PGD/hepA/MGPG861 Approved April 2017, NHSH 14_55_v5 Approved May 2016 and NHS Tayside – Hepatitis A PGD.	
Date of change	Summary of Changes	Section heading
February 2019	Transferred to NoS PGD template at the time of 2 year review. NHSH, NHST, NHSO, NHSS and NHSWI added to PGD.	Throughout
February 2019	Those who are likely to progress to injecting, sexual partners of injecting drug users, and non-injecting users who are living with current injectors, men who have sex with men added.	Inclusion Criteria
March 2019	Statement added regarding storage in NHST only.	Storage
June 2019	Exclusion criteria changed to include individuals under 12 months of age, and specific exclusion criteria of individuals under 2 months of age added for NHST only.	Exclusion criteria
June 2019	Statement added regarding the off-label use of Havrix® Junior Monodose® and VAQTA® Paediatric in individuals under 12 months of age.	Name form and strength of medicine
March 2021	PGD Amended to include NHS Orkney for OHS inclusion.	Inclusion criteria

NOS Identifier: NoS/PGD/HepA/MGPG1036**Keyword(s):** PGD Patient Group Direction hepatitis A vaccine nurse pharmacist hepatitis Havrix Monodose Avaxim VAQTA adult paediatric

Policy Statement: It is the responsibility of individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of individual safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	February 2019
	Completed:	May 2019
	Approved:	June 2019 (published – July 2019)
	Amended:	March 2021

This document is also available in large print and other formats and languages, upon request. Please contact the appropriate NHS Board Communications Department:

NHS Grampian & NHS Orkney 01224 551116 or 01224 552245.

NHS Highland 01463 704722

NHS Shetland 01595 743310

NHS Tayside 01382 424138

NHS Western Isles coms.wi@nhs.net

N.B. This PGD was impact assessed on 25/06/2019.


Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

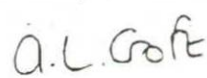
PGD Developed/Reviewed by;

<p>Medical practitioner</p>	<p>Name: Dr Diana Webster Health Board: NHSG Title: Consultant in Public Health Contact email: diana.webster@nhs.net Signature ... </p>
<p>Senior representative of the professional group who will provide care under the direction.</p>	<p>Name: Tina McMichael Health Board: NHST Title: Advanced Nurse Specialist (Health Protection) Contact email: t.mcmichael@nhs.net Signature ... </p>
<p>Lead author</p>	<p>Name: Frances Adamson Health Board: NHSG Title : Medicines Management Specialist Nurse Contact email: f.adamson@nhs.net Signature ... </p>
<p>Pharmacist</p>	<p>Name: Wendy Lycett Health Board: NHSO Title : Principal Pharmacist Contact email: wendylcett@nhs.net Signature ... </p>

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Thomson		July 2019

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Amanda Croft		July 2019

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	Lead Author: Medicines Management Specialist Nurse NHSG
Wendy Lycett	Pharmacist: Principal Pharmacist NHSO
Dr Diana Webster	Medical Practitioner: NHSG
Tina McMichael	Senior Representative: Advanced Nurse Specialist (Health Protection) NHST
Fiona Browning	Health Protection Nurse Specialist NHSG
Dr Ambreen Butt	Consultant in Sexual Health and HIV NHSG
Lorraine McKee	Health Protection Nurse Specialist NESH
Craig Mitchell	Health Protection Nurse Specialist NHSWI
Rhiannon Sharp	Lead Nurse Travel Clinic GO Health NHSG

Patient Group Direction For The Administration Of Hepatitis A Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Clinical indication to which this PGD applies

<p>Definition of situation/Condition</p>	<p>This Patient Group Direction (PGD) will authorise approved healthcare professionals to administer Hepatitis A vaccine for active immunisation of individuals at high risk of contracting Hepatitis A.</p> <p>This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book Chapter 17, TRAVAX, NaTHNaC, the individual Summary of Product Characteristics (SmPC) and local policies and procedures as applicable.</p>
<p>Inclusion criteria</p>	<ul style="list-style-type: none"> • Travellers to areas of moderate to high Hepatitis A endemicity, and those going to reside abroad, particularly if sanitation and food hygiene are likely to be poor. • Those with chronic liver disease including those with chronic hepatitis B or C infection. • Haemophiliacs. • People whose sexual behaviour is likely to put them at risk of infection including men who have sex with men (MSM). • People who Inject Drugs (PWIDs), those who are likely to progress to injecting, sexual partners of injecting drug users, and non-injecting users who are living with current injectors. • Close and household contacts within 14 days of exposure to the index case. Advice on who would require vaccination in these circumstances will be given by the Health Protection Team. Those with a history of jaundice or who have lived for a long time in endemic areas may have become 'naturally' immune as a result of infection and this immunity lasts for life. Individual's blood can be tested for Hepatitis A IgG antibodies and vaccination is not necessary if these antibodies are present. • Immunisation may be indicated in children and adults of any age, where there is a confirmed cluster/outbreak of serious disease in a closed setting and should be on the advice of individual Board Health Protection Teams. <p>Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.</p>

	<p>The following inclusions apply only in NHS Grampian and NHS Orkney:</p> <ul style="list-style-type: none"> • Laboratory workers who are working directly with the virus. • Staff and residents of some residential institutions (after local risk assessment). • Workers at risk of repeated exposure to raw sewage following local risk assessment. • Individuals who work with primates that are susceptible to Hepatitis A infection.
<p>Exclusion criteria</p>	<ul style="list-style-type: none"> • Under 12 months of age. • Individuals with current acute systemic or febrile illness. • Have had an anaphylactic reaction to a previous dose of the vaccine or to any of the components of the vaccine. • Individuals at occupational risk (not an exclusion in NHS Grampian or NHS Orkney). • No valid consent. <p>The following exclusion criteria applies in NHS Tayside only;</p> <ul style="list-style-type: none"> • Under 2 months of age.
<p>Precautions and special warnings</p>	<p>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered, in order to prevent symptoms of the illness being wrongly attributed with any adverse effects of the vaccine.</p> <p>VAQTA® and VAQTA® Paediatric - use caution when vaccinating latex-sensitive individuals since the syringe plunger stopper and tip cap contain dry natural latex rubber that may cause allergic reactions.</p> <p>In individuals who are immunocompromised, response may be impaired and further vaccinations may be necessary.</p> <p>Individuals with a Bleeding Disorder - An individual risk assessment should be undertaken prior to vaccination. As with any intramuscular (IM) vaccination, the injection should be given with caution to individuals with thrombocytopenia or any coagulation disorder as bleeding may occur following an intramuscular administration to these subjects. Therefore, individuals with known bleeding disorders or on anticoagulant therapy should receive the vaccine by deep subcutaneous injection route to reduce the risk of bleeding. Individuals should be informed of the risk of developing haematoma and what to do if this occurs.</p>

<p>Action if excluded from treatment</p>	<p>Medical advice must be sought – refer to relevant medical practitioner. If clarification is required about an individual meeting the exclusion criteria advice can be sought from the local Health Protection team.</p> <p>The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records.</p> <p>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged.</p> <p>Document the reason for exclusion under the PGD and any action taken in the individual’s appropriate clinical records, and inform the appropriate clinician, e.g. GP/District Nurse/Health Visitor/Family Nurse/Midwife/Paediatrician.</p>
<p>Action if treatment is declined</p>	<p>Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available in print here. Document advice given and decision reached.</p> <p>Inform/refer to the relevant medical practitioner if individual/person with parental responsibility declines treatment.</p> <p>Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.</p>

Description of vaccine available under the PGD

<p>Name form and strength of medicine</p>	<p>Hepatitis A (inactivated) vaccine (adsorbed) e.g.</p> <p>Havrix® Monodose® vaccine, Hepatitis A virus 1440 ELISA units in a pre-filled syringe or vial</p> <p>Havrix® Junior Monodose® vaccine, Hepatitis A virus 720 ELISA units in a pre-filled syringe or vial</p> <p>AVAXIM®, Hepatitis A virus, (GBM strain) 160 U*, suspension for injection in a pre-filled syringe</p> <p>VAQTA® Adult, Hepatitis A virus (strain CR 326F) 50 U* suspension for injection in a pre-filled syringe or vial</p>
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	<p>VAQTA® Paediatric, Hepatitis A virus (strain CR 326F) 25 U* suspension for injection in a pre-filled syringe or vial</p> <p>*In the absence of an international standardised reference, the antigen content is expressed using an in-house method of the manufacturer.</p> <p>An appropriate vaccine product should be selected for the individual see Dosage/Maximum total dose section.</p> <p>N.B. NHS Tayside - The use of Havrix® Junior Monodose® and VAQTA® Paediatric in individuals less than 12 months of age constitutes an off-label use of the vaccines. The person with parental responsibility should be informed prior to the administration of the vaccine.</p> <p>All Hepatitis A vaccines can be used interchangeably and Havrix®, AVAXIM®, VAQTA® vaccines are all thiomersal free.</p>
<p>Legal status</p>	<p>Hepatitis A monovalent vaccine is a Prescription-only Medicine (PoM).</p> <p>N.B. Administration of Havrix® Monodose or Havrix® Junior Monodose® by deep subcutaneous injection to individuals with a bleeding disorder is an off-label administration but is consistent 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.</p>

Dosage/Maximum total dose	Dose of 0.5mL or 1.0mL per administration depending on the age of the individual and vaccine product used.			
	Vaccine	Ages	Dose	Timing of Booster
	Havrix® Monodose	16 years or over	1.0mL	After 6-12 months, up to 60 months
	Havrix® Junior Monodose®	One to 15 years*	0.5mL	After 6-12 months, up to 36 months
		**2 months up to one year	0.5mL	
	Avaxim®	16 years or over	0.5mL	After 6-12 months, up to 36 months
Vaccine	Ages	Dose	Timing of Booster	
VAQTA® Paediatric	One to 17 years*	0.5mL	After 6-18 months or 6-12 months if different primary vaccine	
	**2 months up to one year	0.5mL		
VAQTA® Adult	18 years and over	1.0mL	After 6-18 months or 6-12 months if different primary vaccine	
<p>Due to the current global shortage of adult Hepatitis A vaccines the following temporary guidance is approved by the Joint Committee on Vaccination and Immunisation (JCVI) for health professionals in the UK:</p> <ul style="list-style-type: none"> • Hepatitis A vaccine use should be prioritised for high risk travellers; a thorough risk assessment will help ensure vaccine recommendations are appropriate. • If an adult monovalent Hepatitis A vaccine is not available immunocompetent adults can be given a single priming dose of either paediatric monovalent Hepatitis A or adult combination Hepatitis A/B vaccine*. 				

	<ul style="list-style-type: none"> • Non Hepatitis A immune HIV positive people should preferentially receive standard adult antigen content monovalent Hepatitis A as a priming dose due to the poorer response rates to vaccine in this group. • If an adult monovalent Hepatitis A vaccine is not available then adults that have been primed with adult monovalent Hepatitis A can be given a booster dose of either paediatric monovalent Hepatitis A or adult combination Hepatitis A/B vaccine*. • Adults that have been primed with adult monovalent Hepatitis A can have their booster dose delayed beyond the recommended 12 months, to five years, in most circumstances. <p>* The use of the paediatric vaccines VAQTA® Paediatric in adults aged >17 years and Havrix® Junior Monodose® adults aged >15 years constitutes an off-label use of the vaccine and should be discussed with the individual prior to administering the vaccine.</p> <p>**N.B. NHS Tayside - The use of Havrix® Junior Monodose® and VAQTA® Paediatric in individuals less than 12 months of age constitutes an off-label use of the vaccines. The person with parental responsibility should be informed prior to the administration of the vaccine.</p>
<p>Frequency of dose/Duration of treatment</p>	<p>Primary course (Single dose): Vaccination should ideally occur preferably at 4 weeks and at least 2 weeks prior to possible exposure to infection with Hepatitis A.</p> <p>For travelers, vaccine should preferably be given at least two 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 monovalent Hepatitis A vaccine, the vaccine may provide some protection before antibodies can be detected using current assays.</p> <p>Reinforcing immunization (Booster dose): For those who require long-term, or subsequent, protection against infection caused by Hepatitis A virus a single reinforcing dose (see table above) should be given leaving a minimum interval of 6-12 months after the first dose. Hepatitis A containing vaccine may be used interchangeably, as appropriate, to complete a course.</p> <p>N.B. When Hepatitis A vaccine is in short supply, delayed boosting should be considered for fully primed individuals. Boosting can be delayed for up to 5 years in most situations.</p>

	<p>Individuals who have been primed with half the licensed antigen dose should be considered for boosting after 1 year.</p> <p>Ongoing risk: A further booster at 25 years is indicated for those at ongoing risk.</p>
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of administration	<p>Administration of the vaccine should be given by Intramuscular (IM) Injection. In children over the age of one year and adults the deltoid region of the upper arm is the recommended site. The anterolateral (outer) thigh muscle is the recommended site in infants under one year of age.</p> <p>This vaccine should not be given by the intravenous or intradermal routes under any circumstances.</p> <p>Individuals with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding. The needle should be inserted at a 45° angle to the skin and the skin should be bunched, not stretched. Pressure (no rubbing) should be applied to the injection site for at least 5 minutes following vaccination.</p> <p>When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to the Hepatitis A vaccine. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records.</p> <p>Shake before injection to obtain a homogeneous suspension. The vaccine should be visually inspected before administration for any foreign particulate matter.</p>
Quantity to be administered	See Dose/Maximum total dose and Frequency/Duration of treatment sections above.
Storage requirements	<p>Vaccine will be stored in a temperature controlled refrigerator between +2°C to +8°C. Refrigerators should have maximum and minimum temperatures recorded daily.</p> <p>Store in original packaging in order to protect from light.</p>

	<p>Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.</p> <p>The following applies within NHS Tayside only; Stability data indicates that Havrix[®] Monodose[®] and Havrix[®] Junior Monodose[®] vaccine is stable at temperatures up to 25°C for 3 days. This PGD may therefore be used by NHS Tayside staff to administer vaccine that has not exceeded these temperature and time parameters. Use of the vaccine that has been stored between +8°C and +25°C constitutes an off-label use of the vaccine and should be discussed with the individual prior to administering the vaccine.</p>
Follow-up (if applicable)	<p>Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.</p>
Advice (Verbal)	<p>Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions.</p> <p>Advise individual of preventative measures to reduce exposure to Hepatitis A including careful attention to food and water hygiene and scrupulous hand washing.</p> <p>Individuals should be advised that the vaccine will not provide full protection until 12 to 15 days after administration.</p> <p>If serious adverse or persistent effects occur, the individual/person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24.</p> <p>When administration is postponed advise the individual/person with parental responsibility when to return for vaccination.</p> <p>If appropriate, advise the individual/person with parental responsibility when subsequent doses are due and if any follow up is required.</p>
Advice (Written)	<p>The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.</p>

	<p>More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation</p>
<p>Identifying and managing possible adverse reactions</p>	<p>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.</p> <p>The most commonly seen reactions are minor local injection site reactions such as induration, oedema, pain and redness. A small painless nodule may form at the injection site.</p> <p>Hepatitis A vaccine is generally well tolerated. Any undesirable effects are usually mild and confined to the first few days after vaccination.</p> <p>Other effects reported include headache, fever, malaise, fatigue, nausea, irritability, diarrhoea and loss of appetite.</p> <p>As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.</p> <p>This list is not exhaustive. Please also refer to current BNFC/BNF and manufacturers SmPC for details of all potential adverse reactions.</p> <p>BNFC/BNF: https://about.medicinescomplete.com/</p> <p>SmPC/PIL/Risk Minimisation Material: https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory</p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p> <p>Report any severe reactions or reactions to any ▼ vaccines using the MHRA using the Yellow Card System. https://yellowcard.mhra.gov.uk/</p>
<p>Facilities and supplies required</p>	<p>The following are to be available at sites where the vaccine is to be administered:</p> <ul style="list-style-type: none"> • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit).

	<ul style="list-style-type: none"> • An acceptable level of privacy to respect individual’s right to confidentiality and safety. • Resuscitation equipment. • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection. • Access to a working telephone. • Another competent adult, who can summon urgent emergency support if required should ideally be present. • Access to medical support (this may be via the telephone). • Approved equipment for the disposal of used materials. • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel. • A copy of the current PGD in print or electronically.
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Characteristics of staff authorised to administer medicine under PGD

Professional qualifications	Registered Nurses as recognised by the Nursing and Midwifery Council (NMC) and Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).
Specialist competencies	<p>Approved by the organisation as:</p> <ul style="list-style-type: none"> • Competent to assess the individual’s/person with parental responsibility capacity to understand the nature and purpose of vaccination in order to give or refuse consent. • Competent to undertake administration of the vaccine and discuss issues related to vaccination. • Competent in the handling and storage of vaccines, and management of the “cold chain” in accordance with relevant local policy and guidance. • Competent to work under this PGD.
Ongoing training and competency	<p>All professionals working under this PGD must:</p> <ul style="list-style-type: none"> • Have undertaken PGD training as required/set out by each individual Health Board. • Have undertaken immunisation training where available. • Have attended basic life support training which is required to be updated annually. • Have undertaken NHS e-anaphylaxis training or equivalent (including annual updates) which covers all aspects of the identification and management of anaphylaxis. • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. • Have knowledge and familiarity of the following; <ul style="list-style-type: none"> ○ Current edition of the Green Book

	<ul style="list-style-type: none"> ○ SmPC for the vaccine to be administered in accordance with this PGD ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board ○ Relevant Scottish Government Health Directorate or Public Health England advice.
Responsibilities of professional manager(s)	<p>Professional manager(s) will be responsible for;</p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.</p>

Documentation

Authorisation of administration	<p>Nurses and Midwives working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the vaccine specified in this PGD by their Professional Line Manager/Consultant/Practice GPs.</p> <p>Pharmacists working within NHS Grampian only can be authorised to administer the vaccine specified in this PGD by their Director of Pharmacy.</p> <p>All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).</p> <p>A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.</p>
Record of administration	<p>An electronic or paper record for recording the screening of individuals and the subsequent administration or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:</p> <ul style="list-style-type: none"> ● Date and time of vaccine administration ● Individuals name and CHI ● Exclusion criteria, record why the vaccine was not administered, if applicable ● Record that valid consent to treatment under this PGD was obtained

	<ul style="list-style-type: none"> • The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine • Record of any adverse effects (advise individuals GP/relevant medical practitioner) <p>Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate.</p> <ul style="list-style-type: none"> • Consent forms • Child Health Information Services if appropriate • Hand-held records such as red book if appropriate • Individual's GP records if appropriate • Secondary Care Medical Notes • Occupational health systems • Individual service specific systems 																		
Audit	<p>All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.</p>																		
References	<p>Electronic Medicines Compendium</p> <table border="1" data-bbox="523 1294 1382 1729"> <thead> <tr> <th>Vaccine</th> <th>Date of Revision</th> <th>Date Accessed</th> </tr> </thead> <tbody> <tr> <td>Havrix[®] Monodose</td> <td>09/12/16</td> <td>07/02/19</td> </tr> <tr> <td>Havrix[®] Junior Monodose[®]</td> <td>09/12/16</td> <td>07/02/19</td> </tr> <tr> <td>AVAXIM[®]</td> <td>15/05/18</td> <td>07/02/19</td> </tr> <tr> <td>VAQTA[®] Paediatric</td> <td>03/02/17</td> <td>07/02/19</td> </tr> <tr> <td>VAQTA[®] Adult</td> <td>03/02/17</td> <td>07/02/19</td> </tr> </tbody> </table> <p>British National Formulary for Children and the British National Formulary https://about.medicinescomplete.com/ accessed 07/02/19.</p> <p>Department of Health (2006): Immunisation against Infectious Disease [Green Book]</p>	Vaccine	Date of Revision	Date Accessed	Havrix [®] Monodose	09/12/16	07/02/19	Havrix [®] Junior Monodose [®]	09/12/16	07/02/19	AVAXIM [®]	15/05/18	07/02/19	VAQTA [®] Paediatric	03/02/17	07/02/19	VAQTA [®] Adult	03/02/17	07/02/19
Vaccine	Date of Revision	Date Accessed																	
Havrix [®] Monodose	09/12/16	07/02/19																	
Havrix [®] Junior Monodose [®]	09/12/16	07/02/19																	
AVAXIM [®]	15/05/18	07/02/19																	
VAQTA [®] Paediatric	03/02/17	07/02/19																	
VAQTA [®] Adult	03/02/17	07/02/19																	

	<p>https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</p> <p>American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.</p>
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Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Hepatitis A Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

Appendix 2

**Healthcare Professionals Authorisation to Administer Vaccine
 Under Patient Group Direction**

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.

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 Highland, Orkney, Shetland, Tayside and Western Isles**

Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date