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## **PATIENT GROUP DIRECTION (PGD)**

Administration of Hepatitis A virus (inactivated) vaccine (adsorbed) to individuals considered at high risk of exposure to hepatitis A or post exposure to hepatitis A virus in accordance with national recommendations.

This PGD is for the administration of Hepatitis A virus (inactivated) vaccine (adsorbed) by registered nurses and pharmacists<sup>1</sup>.

Reference no: Hepatitis A vaccine PGD  
Version no: V01.00  
Valid from: 01 November 2017  
Review date: 01 May 2019  
Expiry date: 31 October 2019

**Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS in line with national recommendations.**

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)<sup>2</sup>. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH [HMR2012 SCHEDULE 16 Part 2](#).**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended.

Operation of this PGD is the responsibility of commissioners and service providers.

**INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from:

<https://www.gov.uk/government/collections/immunisation>

Any concerns regarding the content of this PGD should be addressed to:

[immunisation@phe.gov.uk](mailto:immunisation@phe.gov.uk)

<sup>1</sup> This may include pharmacists working for NHS commissioned primary care providers, substance misuse or sexual health clinics. This PGD is not relevant to privately provided community pharmacy services.


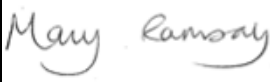

<sup>2</sup> This includes any relevant amendments to legislation (eg [2013 No235](#), [2015 No.178](#) and [2015 No.323](#)).

## Change history

Version number	Change details	Date
V01.00	New PHE Hepatitis A vaccine PGD	12 October 2017

## 1. PGD template development

This PGD template has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
<b>Pharmacist</b> (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		12/10/2017
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		12/10/2017
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		12/10/2017

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Delivery Board.

### Expert Panel

Name	Designation
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sema Mandal	Medical Consultant Epidemiologist, Public Health England
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Matthew Olley	Immunisation Manager, Public Health England / NHS England London Region
Lisa Rees	Medicines Management Pharmacist, Bristol Clinical Commissioning Group
Tushar Shah	Pharmacy Advisor, NHS England London Region
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East

## 2. Organisational authorisations

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

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

**NHS ENGLAND MIDLANDS AND EAST (CENTRAL MIDLANDS)** authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
<b>General medical practices from which NHS England Midlands and East (Central Midlands) commissions immunisation services</b>
Limitations to authorisation

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Medical Director, NHS England Midlands and East (Central Midlands)	Dr Aly Rashid		15 <sup>th</sup> November 2017

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Local enquiries regarding the use of this PGD may be directed to:

For **Bedfordshire, Hertfordshire, Luton and Milton Keynes** - [england.immsqa@nhs.net](mailto:england.immsqa@nhs.net) - the (Central Midlands) South public health/screening and immunisation team

For **Leicestershire, Lincolnshire and Northamptonshire** – [england.limms@nhs.net](mailto:england.limms@nhs.net) - the (Central Midlands) North and Central public health/screening and immunisation team.

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

### 3. Characteristics of staff

<p><b>Qualifications and professional registration</b></p>	<p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> <li>• nurses currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists registered with the General Pharmaceutical Council (GPhC).</li> </ul>
<p><b>Additional requirements</b></p>	<p>Additionally practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it</li> <li>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>• must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using patient group directions)</li> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (“<a href="#">The Green Book</a>”), and national and local immunisation programmes</li> <li>• must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards for Immunisation Training (2005)</a></li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>• must be competent in the handling and storage of vaccines, and management of the “cold chain”</li> <li>• must be competent in the recognition and management of anaphylaxis</li> <li>• must have access to the Patient Group Direction and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul> <p><b>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</b></p>
<p><b>Continued training requirements</b></p>	<p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information.</p> <p>Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.</p>

#### 4. Clinical condition or situation to which this PGD applies

<p><b>Clinical condition or situation to which this PGD applies</b></p>	<p>Indicated for the active immunisation of individuals against hepatitis A infection in accordance with national recommendations including:</p> <ul style="list-style-type: none"> <li>• <a href="#">Chapter 7</a> and <a href="#">Chapter 17</a> of Immunisation Against Infectious Disease: “The Green Book”</li> <li>• <a href="#">NaTHNaC</a> recommendations for hepatitis A vaccination for travel</li> <li>• <a href="#">PHE hepatitis A vaccination temporary recommendations</a></li> <li>• <a href="#">Public health control and management of hepatitis A</a> guidance</li> </ul>
<p><b>Criteria for inclusion</b></p>	<p>Adults and children over 1 year old who:</p> <ul style="list-style-type: none"> <li>• intend to travel, where hepatitis A vaccination is currently recommended for travel by NaTHNaC (see the <a href="#">Travel Health Pro</a> website for country-specific advice on hepatitis A vaccine recommendations)</li> <li>• are at risk of hepatitis A infection because of their sexual behaviour, including men who have sex with men (MSM), see <a href="#">Additional information</a> section</li> <li>• are people who inject drugs (PWID)</li> <li>• are haemophiliac</li> <li>• have chronic liver disease (including alcoholic cirrhosis, chronic hepatitis B, chronic hepatitis C, autoimmune hepatitis, primary biliary cirrhosis)</li> </ul> <p>Adults and children from 2 months old who:</p> <ul style="list-style-type: none"> <li>• are recommended hepatitis A vaccine in accordance with <a href="#">Public health control and management of hepatitis A</a> guidance</li> </ul>
<p><b>Criteria for exclusion<sup>3</sup></b></p>	<p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are under one year of age, with the exception of those over 2 months of age requiring vaccination in accordance with <a href="#">Public health control and management of hepatitis A</a> guidance</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of hepatitis A vaccine or to any component of the vaccine (including trace components from the manufacturing process which may include formaldehyde and/or neomycin, see SPCs)</li> <li>• are at increased risk of hepatitis A infection because of their occupation (eg employees in day care centres, nursing, medical and paramedical personnel in hospitals and institutions, sewage workers and food packagers or handlers)</li> <li>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)</li> </ul>
<p><b>Cautions including any relevant action to be taken</b></p> <p>Continued over page</p>	<p>VAQTA<sup>®</sup>, and VAQTA<sup>®</sup> Paediatric, syringe plunger stopper and tip cap contain dry natural latex rubber that may cause allergic reactions. As a precaution, if an individual has a history of severe (ie anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain latex should not be administered, unless the benefit of vaccination outweighs the risk of an allergic reaction to the vaccine. If possible, an alternative latex-free vaccine should be administered</p>

<sup>3</sup> Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

<p><b>Cautions including any relevant action to be taken</b> (continued)</p>	<p>(eg Avaxim<sup>®</sup> or Havrix<sup>®</sup>).</p> <p>Individuals who are immunosuppressed or have HIV infection may not make a full antibody response and revaccination on cessation of treatment/recovery may be required. This should be discussed with the appropriate/relevant specialist.</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><b>Action to be taken if the patient is excluded</b></p>	<p>Individuals under one year of age are not recommended pre-exposure hepatitis A vaccination. Individuals from 2 months of age may be considered for immunisation in accordance with <a href="#">Public health control and management of hepatitis A</a>. Where vaccine is not recommended (and even when it is), the importance of stringent hygiene measures should be reinforced.</p> <p>Individuals 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 clinician for specialist advice and appropriate management.</p> <p>Individuals who are solely at occupational risk of hepatitis A exposure should be referred to their employer's occupational health provider for vaccination.</p> <p>Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.</p>
<p><b>Action to be taken if the patient or carer declines treatment</b></p>	<p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration.</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document advice given and the decision reached.</p> <p>In a GP practice setting, inform or refer to the GP as appropriate.</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>As per local policy</p>



## 5. Description of treatment

<p><b>Name, strength &amp; formulation of drug</b></p>	<p>Hepatitis A (inactivated) vaccine (adsorbed) eg:</p> <ul style="list-style-type: none"> <li>• <b>Havrix<sup>®</sup> Monodose<sup>®</sup></b> vaccine, hepatitis A virus 1440 ELISA units in a pre-filled syringe or vial</li> <li>• <b>Havrix<sup>®</sup> Junior Monodose<sup>®</sup></b> vaccine, hepatitis A virus 720 ELISA units in a pre-filled syringe or vial</li> <li>• <b>AVAXIM<sup>®</sup></b>, hepatitis A virus, (GBM strain) 160 U*, suspension for injection in a pre-filled syringe</li> <li>• <b>VAQTA<sup>®</sup> Adult</b>, hepatitis A virus (strain CR 326F) 50 U* suspension for injection in a pre-filled syringe or vial</li> <li>• <b>VAQTA<sup>®</sup> Paediatric</b>, hepatitis A virus (strain CR 326F) 25 U* suspension for injection in a pre-filled syringe or vial</li> </ul> <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 patient see <a href="#">Dose and frequency of administration</a> section and <a href="#">PHE hepatitis A vaccination temporary recommendations</a>.</p>
<p><b>Legal category</b></p>	<p>Prescription only medicine (POM)</p>
<p><b>Black triangle▼</b></p>	<p>No</p>
<p><b>Off-label use</b></p>	<p>Hepatitis A vaccine may be administered off-label to infant hepatitis A contacts from 2 months of age in accordance with <a href="#">Public health control and management of hepatitis A</a> guidance.</p> <p>During vaccine supply shortages it may be appropriate to provide adults with a paediatric dose of hepatitis A vaccine off-label, or a combination vaccine product (see alternative PGD), as a dose sparing option to preserve adult monovalent hepatitis A vaccine stock for groups most likely to benefit. Such off-label administration may be undertaken under this PGD where it is in accordance <a href="#">PHE hepatitis A vaccination temporary recommendations</a>.</p> <p>Please refer to the most up to date guidance as appropriate from PHE.</p> <p>Administration of Havrix<sup>®</sup> Monodose or Havrix<sup>®</sup> Junior Monodose<sup>®</sup> by deep subcutaneous injection to patients with a bleeding disorder is off-label administration but is in line with advice in <a href="#">Chapter 4</a> and <a href="#">Chapter 22</a> of “The Green Book”. Licensed administration of another brand of hepatitis vaccine where available may be considered as an alternative.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p>
<p><b>Route / method of administration</b></p> <p>Continued over page</p>	<p>Administer by intramuscular injection into the deltoid region of the upper arm. In small infants the anterolateral thigh may be used. The buttock should not be used because vaccine efficacy may be reduced.</p> <p>When administering at the same time as other vaccines, care should</p>

<p><b>Route / method of administration</b> (continued)</p>	<p>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.</p> <p>Where, in accordance with <a href="#">PHE hepatitis A vaccination temporary recommendations</a>, the hepatitis A vaccine dose is provided as two simultaneous doses of a hepatitis A containing vaccine, these should be administered simultaneously at the same site.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see "The Green Book" <a href="#">Chapter 4</a>).</p> <p>The suspension for injection may sediment during storage. Shake the vaccine well before administration to obtain a slightly opaque, white suspension.</p> <p>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.</p> <p>The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>																								
<p><b>Dose and frequency of administration</b></p>	<p>Current UK licensed hepatitis A vaccines contain different concentrations of antigen per millilitre (see table below). The choice of vaccine and dose used should be guided by the individual's age, immunocompetence and dose recommendations in the vaccine manufacturer's SPC. During times of hepatitis A vaccine supply shortages, off-label administration may be appropriate in accordance with <a href="#">PHE hepatitis A vaccination temporary recommendations</a>.</p> <table border="1" data-bbox="550 1288 1458 1892"> <thead> <tr> <th>Vaccine</th> <th>Age (licenced use)</th> <th>Dose</th> <th>Volume</th> </tr> </thead> <tbody> <tr> <td><b>Havrix Monodose<sup>®</sup></b></td> <td>16 years or over</td> <td>1440 units ELISA</td> <td>1.0ml</td> </tr> <tr> <td><b>Havrix<sup>®</sup> Junior Monodose<sup>®</sup></b></td> <td>One to 15 years</td> <td>720 units ELISA</td> <td>0.5ml</td> </tr> <tr> <td><b>Avaxim<sup>®</sup></b></td> <td>16 years or over</td> <td>160 antigen units*</td> <td>0.5ml</td> </tr> <tr> <td><b>VAQTA Adult<sup>®</sup></b></td> <td>18 years of age and older</td> <td>50 units*</td> <td>1ml</td> </tr> <tr> <td><b>VAQTA Paediatric<sup>®</sup></b></td> <td>One to 17 years</td> <td>25 units*</td> <td>0.5ml</td> </tr> </tbody> </table> <p>*in the absence of an international standardised reference, the antigen content is expressed using an in-house method of the manufacturer</p>	Vaccine	Age (licenced use)	Dose	Volume	<b>Havrix Monodose<sup>®</sup></b>	16 years or over	1440 units ELISA	1.0ml	<b>Havrix<sup>®</sup> Junior Monodose<sup>®</sup></b>	One to 15 years	720 units ELISA	0.5ml	<b>Avaxim<sup>®</sup></b>	16 years or over	160 antigen units*	0.5ml	<b>VAQTA Adult<sup>®</sup></b>	18 years of age and older	50 units*	1ml	<b>VAQTA Paediatric<sup>®</sup></b>	One to 17 years	25 units*	0.5ml
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Continued over page

<p><b>Dose and frequency of administration</b> (continued)</p>	<p><b>Primary course:</b> single dose (see table above). Vaccination should ideally occur at least 2 weeks prior to possible exposure to infection with hepatitis A.</p> <p>For travellers, 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><b>Reinforcing immunisation:</b> 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>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>In those in whom priming may not have been optimal, eg immunocompromised HIV positive individuals, those with chronic liver disease, and persons over 60 years who received half dose antigen content for priming, a further prime before boost (prime-prime-boost) is recommended with an interval of at least 4 months between doses (see <a href="#">PHE hepatitis A vaccination temporary recommendations</a>).</p> <p>Until further evidence is available on persistence of protective immunity, a further booster at 25 years is indicated for those at ongoing risk.</p> <p>In accordance with <a href="#">PHE hepatitis A vaccination temporary recommendations</a> in some circumstances it may be appropriate to administer an adult a single dose of hepatitis A vaccine as two simultaneous administrations of a hepatitis A containing vaccine with a lower antigen content (ie two paediatric doses).</p>
<p><b>Duration of treatment</b></p>	<p>Dependent of vaccine schedule, see <a href="#">Dose and frequency of administration</a>.</p>
<p><b>Quantity to be supplied / administered</b></p>	<p>Dose of 0.5ml or 1.0ml per an administration depending on the age of the individual and vaccine product used, see <a href="#">Dose and frequency of administration</a>.</p>
<p><b>Supplies</b></p>	<p>Hepatitis A vaccine is not usually centrally supplied and should be obtained directly from manufacturers/wholesalers. During periods of nationally relevant outbreak supplies may be secured for outbreak control and should be accessed in accordance with PHE recommendations.</p> <p>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see <a href="#">protocol for ordering storage and handling of vaccines</a> and Green Book <a href="#">Chapter 3</a>).</p>

<p><b>Storage</b></p>	<p>Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.</p> <p>Stability data indicate that Havrix® Monodose® and Havrix® Junior Monodose® vaccine 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. This PGD may be used to administer vaccine that has not exceeded these stability data parameters.</p> <p>Breaches in the cold chain should be reported to the Screening and Immunisation Team in line with local arrangements. Vaccine that has been stored outside the conditions stated above should be quarantined and further advice should be sought from the local Screening and Immunisation or Health Protection Team.</p>
<p><b>Disposal</b></p>	<p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the <a href="#">technical memorandum 07-01</a>: Safe management of healthcare waste (Department of Health, 2013).</p>
<p><b>Drug interactions</b></p>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment.</p> <p>May be given at the same time as other vaccines.</p> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<p><b>Identification &amp; management of adverse reactions</b></p>	<p>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.</p> <p>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.</p> <p>Hypersensitivity reactions and anaphylaxis can occur but are very rare.</p> <p>A detailed list of adverse reactions is available in the SPC , which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<p><b>Reporting procedure of adverse reactions</b></p>	<p>Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme at: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p>

<b>Written information to be given to patient or carer</b>	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
<b>Patient advice / follow up treatment</b>	<p>Inform the individual/carer of possible side effects and their management.</p> <p>The individual/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>When applicable, advise individual/carer when the subsequent dose is due.</p> <p>When administration is postponed advise the individual/carer when to return for vaccination.</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>
<b>Special considerations / additional information</b>	<p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone.</p> <p><a href="#">PHE hepatitis A vaccination temporary recommendations</a> were issued by PHE in July 2017 in light of an ongoing hepatitis A outbreak, primarily affecting men who have sex with men (MSM), and a global shortage of hepatitis A vaccine affecting UK supply. These recommendations advise that all MSM without reliable evidence of previous hepatitis A vaccination or infection attending GUM and HIV clinics should be opportunistically offered hepatitis A vaccination.</p> <p>The <a href="#">PHE hepatitis A vaccination temporary recommendations</a> provide dose-sparing options for hepatitis A vaccine selection, along with additional information and rationale. They should inform selection of which hepatitis A vaccine to administer whilst vaccine shortage affects UK supply.</p> <p>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.</p>
<b>Records</b>	<p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given</li> <li>• name of individual, address, date of birth and GP with whom the individual is registered</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via Patient Group Direction (PGD)</li> </ul>

<p>Continued over page <b>Records</b> (continued)</p>	<p>Records should be signed and dated (or a password controlled immunisers record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Systems team (Child Health Records Department) using the appropriate documentation/pathway as required by any local or contractual arrangement.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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## 6. Key references

<b>Key references</b>	<p><b>Product</b></p> <ul style="list-style-type: none"><li>• Immunisation Against Infectious Disease: The Green Book <a href="#">Chapter 4</a>, last updated June 2012, <a href="#">Chapter 7</a>, last updated 29 September 2016, and <a href="#">Chapter 17</a>, last updated 04 December 2013. <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li><li>• Summary of Product Characteristic for Avaxim<sup>®</sup>, Sanofi Pasteur. Last updated 28 Feb 2017. <a href="https://www.medicines.org.uk/emc/medicine/6206">https://www.medicines.org.uk/emc/medicine/6206</a></li><li>• Summary of Product Characteristic for Havrix<sup>®</sup> Junior Monodose<sup>®</sup>, GlaxoSmithKline UK. Last updated 9 Dec 2016. <a href="https://www.medicines.org.uk/emc/medicine/2040">https://www.medicines.org.uk/emc/medicine/2040</a></li><li>• Summary of Product Characteristic for Havrix<sup>®</sup> Monodose<sup>®</sup>, GlaxoSmithKline UK. Last updated 9 Dec 2016. <a href="https://www.medicines.org.uk/emc/medicine/2041">https://www.medicines.org.uk/emc/medicine/2041</a></li><li>• Summary of Product Characteristic for VAQTA<sup>®</sup> Paediatric, MSD Ltd. Last updated 03 Feb 2017. <a href="https://www.medicines.org.uk/emc/medicine/6206">https://www.medicines.org.uk/emc/medicine/6206</a></li><li>• Summary of Product Characteristic for VAQTA<sup>®</sup> Adult, MSD Ltd. Last updated 03 Feb 2017. <a href="https://www.medicines.org.uk/emc/medicine/6210">https://www.medicines.org.uk/emc/medicine/6210</a></li><li>• NaTHNaC recommendations for hepatitis A vaccination for travel. Accessed 19 July 2017. <a href="https://travelhealthpro.org.uk/news-topic/16/hepatitis-a">https://travelhealthpro.org.uk/news-topic/16/hepatitis-a</a></li><li>• Hepatitis A infection: prevention and control guidance including <a href="#">PHE hepatitis A vaccination temporary recommendations</a> and <a href="#">Public health control and management of hepatitis A</a> guidance. Public Health England. Last updated 4 July 2017. <a href="https://www.gov.uk/government/publications/hepatitis-a-infection-prevention-and-control-guidance">https://www.gov.uk/government/publications/hepatitis-a-infection-prevention-and-control-guidance</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• PHE Immunisation Collection <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• British National Formulary (BNF) and British National Formulary for Children (BNF-C) <a href="http://www.BNF.org">www.BNF.org</a> <a href="https://www.medicinescomplete.com/mc/bnf/current/PHP8291-hepatitis-a-vaccine.htm">https://www.medicinescomplete.com/mc/bnf/current/PHP8291-hepatitis-a-vaccine.htm</a></li><li>• National Minimum Standards for Immunisation Training (2005) <a href="https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards">https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. <a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li><li>• Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. <a href="https://www.rcn.org.uk/professional-development/publications/pub-">https://www.rcn.org.uk/professional-development/publications/pub-</a></li></ul>
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<b>Key references</b> (continued)	<p><a href="#">005336</a></p> <ul style="list-style-type: none"><li>• Protocol for ordering storage and handling of vaccines. April 2014. <a href="https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines">https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines</a></li><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <a href="https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste">https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste</a></li></ul>
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## 7. Practitioner authorisation sheet

### Hepatitis A vaccine PGD v01.00 Valid from: 01/11/2017 Expiry: 31/10/2019

Before signing this PGD, check that the document has had the necessary authorisations in section two. Without these, this PGD is not lawfully valid.

#### Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

#### Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of \_\_\_\_\_ (**INSERT NAME OF PRACTICE**) for the above named health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

#### Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.