UK Health Security Agency

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Hepatitis A Vaccine Patient Group Direction (PGD)

This PGD is for the 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 use by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	Hepatitis A vaccine PGD
Version no:	V04.00
Valid from:	01 November 2021
Review date:	01 May 2023
Expiry date:	31 October 2023

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly-funded immunisation in England 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)[1]. **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 within the designated editable fields provided.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

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/UKHSA PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Contacts listed on page 4 and 5 of this PGD

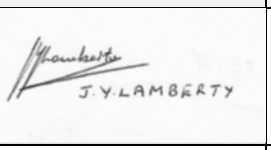
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE Hepatitis A vaccine PGD	12 October 2017
V02.00	PHE Hepatitis A vaccine PGD amended to: • include additional healthcare practitioners in Section 3 • refer to vaccine incident guidelines in off-label and storage sections • remove reference to the 'PHE hepatitis A vaccination temporary recommendations' and associated clinical recommendations for times of vaccine supply shortages • remove reference the protocol for ordering storage and handling of vaccines • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	12 September 2019
V03.00	PHE Hepatitis A vaccine PGD amended to: • insert missing amended paragraph into 'Additional information' section, relating to the hyperlink from the inclusion criteria for MSM.	4 October 2019
V04.00	PHE Hepatitis A vaccine PGD amended to include: • phenylalanine content in Avaxim® vaccine and action to be taken • booster dosing delays still provide protection • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates	8 October 2021

1. PGD development

This PGD has been developed by the following health professionals on behalf of UKHSA

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Jacqueline Lamberty Lead Pharmacist Medicines Governance, UKHSA		12 October 2021
Doctor	Dr Gayatri Amirthalingam Consultant Epidemiologist, Immunisation, Hepatitis and Blood Safety Department, National Infection Service, UKHSA		12 October 2021
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, UKHSA		12 October 2021

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

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHS England and NHS Improvement
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHS England and NHS Improvement South (South West)
Gill Marsh	Principal Screening and Immunisation Manager, NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHS England and NHS Improvement (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)

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.

NHSE&I North East and Yorkshire authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England & Improvement (NHSE&I) commissioned immunisation services providing immunisation services.
Limitations to authorisation
Authorisation is limited to those registered practitioners listed in Section 3 who are employed by organisations/providers commissioned by NHSE&I North East and Yorkshire (NEY) to deliver immunisation programmes within the whole of the NHSE&I region of North East and Yorkshire

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Assistant Medical Director and Responsible Officer, **NHS England and NHS Improvement –NEY**	**Dr James Gossow**		**26/10/2021**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
NHSE&I NEY PGD Governance assurance review (Medicines Optimisation Pharmacist Lead, NHS NECS	**Kurt Ramsden**		**25/10/2021**
NHSE&I NEY PGD Governance assurance review (Screening and immunisation coordinator, North Region | NE and Yorkshire | Yorkshire and the Humber NHS England and NHS Improvement	**Julie Hogarth**		**22/10/2021**

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation teams. See area-specific contacts below:

For North East and North Cumbria Area (i.e. Northumberland, Tyne & Wear, Durham Darlington and Tees and North Cumbria) use the following:
NHS England Screening and Immunisation Team: email england.cane.screeingimms@nhs.net or NECS Medicine Optimisation Pharmacists: Kurt Ramsden: kurtramsden@nhs.net or Sue White: sue.white14@nhs.net

Please note - All North East and North Cumbria PGDs can be found at:
https://medicines.necsu.nhs.uk/resources/patient-group-directions/

For Yorkshire and Humber Area use the following:
West Yorkshire england.wy-screeningandimms@nhs.net
South Yorkshire and Bassetlaw england.sybsit@nhs.net
North Yorkshire and Humber ENGLAND.NYAHSIT@nhs.net or the Health Protection Team Acute Response Centre (ARC): Contact Number: **0113 3860 300**.

Please note - All Yorkshire and Humber PGDs can be found at:
https://www.england.nhs.uk/north-east-yorkshire/our-work/information-for-professionals/pgds/.

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

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 Limitations to authorisation to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	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). Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHS England and NHS Improvement and other sources of medicines information. 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.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals against hepatitis A infection in accordance with national recommendations including: • Chapter 7 and Chapter 17 of Immunisation Against Infectious Disease: "The Green Book" • NaTHNaC - Hepatitis A (travelhealthpro.org.uk) recommendations for hepatitis A vaccination for travel • Public health control and management of hepatitis A guidance
Criteria for inclusion	Adults and children over 1 year old who: • intend to travel, where hepatitis A vaccination is currently recommended for travel by NaTHNaC (see the Travel Health Pro website for country-specific advice on hepatitis A vaccine recommendations) • are at risk of hepatitis A infection because of their sexual behaviour, including men who have sex with men (MSM), see Additional information section • are people who inject drugs (PWID) • have haemophilia • have chronic liver disease (including alcoholic cirrhosis, chronic hepatitis B, chronic hepatitis C, autoimmune hepatitis, primary biliary cirrhosis) Adults and children from 2 months old who: • are recommended hepatitis A vaccine in accordance with Public health control and management of hepatitis A guidance
Criteria for exclusion[2]	Individuals for whom valid consent, or 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). The Patient information leaflet (PIL) for the vaccine to be used should be available to inform consent. Individuals who: • are under one year of age, with the exception of those over 2 months of age requiring vaccination in accordance with Public health control and management of hepatitis A guidance • 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, neomycin, ethanol, phenylalanine (see Cautions), polymixin B, egg products or chicken protein see SPCs) • are at increased risk of hepatitis A infection because of their occupation • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions including any relevant action to be taken Continued over page	VAQTA®, and VAQTA® 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 (anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain latex should not be administered, unless the benefit of

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Cautions including any relevant action to be taken (continued)	vaccination outweighs the risk of an allergic reaction to the vaccine. If possible, an alternative latex-free vaccine should be administered (such as AVAXIM® or Havrix®). 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. Avaxim® vaccine contains 10 microgram phenylalanine in each 0.5 ml dose, which is equivalent to 0.17 microgram/kg for a 60 kg person. Phenylalanine may be harmful for individuals with phenylketonuria (PKU). The amount in the vaccine is unlikely to adversely affect individuals with PKU, but they should be advised Avaxim® vaccine contains 10 micrograms of phenylalanine. These individuals will be well versed as to the amounts they can tolerate in their diet. If available offer an alternative vaccine. Havrix® Monodose® also has trace amino acids, so VAQTA® would be the preferred option. Alternatively, seek advice from the specialist endocrinologist/metabolic physician looking after the individual with PKU to confirm they are content for them to have Avaxim®. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Action to be taken if the patient is excluded	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 Public health control and management of hepatitis A. Where vaccine is not recommended (and even when it is), the importance of stringent hygiene measures should be reinforced. 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. Individuals who are solely at occupational risk of hepatitis A exposure should be referred to their employer's occupational health provider for vaccination. 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. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a prescriber as appropriate.

Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of 'The Green Book'. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Hepatitis A (inactivated) vaccine (adsorbed), either: • **Havrix® Monodose®** vaccine, hepatitis A virus1440 ELISA units in a pre-filled syringe or vial • **Havrix® Junior Monodose®** vaccine, hepatitis A virus 720 ELISA units in a pre-filled syringe or vial • **AVAXIM®**, hepatitis A virus, (GBM strain) 160 U*, suspension for injection in a pre-filled syringe • **VAQTA® Adult**, hepatitis A virus (strain CR 326F) 50 U* suspension for injection in a pre-filled syringe or vial • **VAQTA® Paediatric**, hepatitis A virus (strain CR 326F) 25 U* suspension for injection in a pre-filled syringe or vial *In the absence of an international standardised reference, the antigen content is expressed using an in-house method of the manufacturer. An appropriate vaccine product should be selected for the individual, see Dose and frequency of administration section.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Hepatitis A vaccine may be administered off-label to infant hepatitis A contacts from 2 months of age in accordance with Public health control and management of hepatitis A guidance. Administration of Havrix® Monodose or Havrix® Junior Monodose® by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration but is in line with advice in Chapter 4 and Chapter 17 of 'The Green Book'. Licensed administration of another brand of hepatitis vaccine where available may be considered as an alternative. Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance or any subsequent UKHSA update. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. 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.
Route / method of administration Continued over page	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. When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be

<table>
<tr><td>Route / method of administration
(continued)</td><td>given at least 2.5cm apart. The site at which each was given should be noted in the individual's records.

For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the 'Green Book' Chapter 4.

The suspension for injection may sediment during storage. Shake the vaccine well before administration to obtain a slightly opaque, white suspension.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk</td></tr>
<tr><td>Dose and frequency of administration

Continued over page</td><td>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.

<table>
<tr><th>Vaccine</th><th>Age (licenced use)</th><th>Dose</th><th>Volume</th></tr>
<tr><td>Havrix Monodose®</td><td>16 years or over</td><td>1440 ELISA units</td><td>1.0ml</td></tr>
<tr><td>Havrix® Junior Monodose®</td><td>One to 15 years</td><td>720 ELISA units</td><td>0.5ml</td></tr>
<tr><td>AVAXIM®</td><td>16 years or over</td><td>160 antigen units*</td><td>0.5ml</td></tr>
<tr><td>VAQTA® Adult</td><td>18 years of age and older</td><td>50 units*</td><td>1ml</td></tr>
<tr><td>VAQTA® Paediatric</td><td>One to 17 years</td><td>25 units*</td><td>0.5ml</td></tr>
<tr><td colspan="4">*in the absence of an international standardised reference, the antigen content is expressed using an in-house method of the manufacturer</td></tr>
</table>

Primary course: single dose (see table above).
Vaccination should ideally occur at least 2 weeks prior to possible exposure to infection with hepatitis A.

For travellers, vaccine should preferably be given at least two weeks before departure, but can be given up to the day of departure.

Reinforcing immunisation: for those who require 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. Studies have shown successful boosting can occur even when the second dose is</td></tr>
</table>

Dose and frequency of administration (continued)	delayed for several years, so a course does not need to be re-started. Hepatitis A containing vaccines may be used interchangeably, as appropriate, to complete a course. Until further evidence is available on persistence of protective immunity, a further booster at 25 years is indicated for those at ongoing risk.
Duration of treatment	Dependent of vaccine schedule, see Dose and frequency of administration.
Quantity to be supplied / administered	Dose of 0.5ml or 1.0ml per an administration depending on the age of the individual and vaccine product used, see Dose and frequency of administration.
Supplies	Hepatitis A vaccine is not usually centrally supplied and should be obtained directly from manufacturers/wholesalers unless otherwise advised by the UKHSA. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Storage	Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. 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. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal, refer to PHE Vaccine Incident Guidance or any subsequent UKHSA update.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

Identification and management of adverse reactions	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. 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 are reported less frequently Hypersensitivity reactions and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the SPC , which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of adverse reactions	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 or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
Patient advice / follow up treatment	Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. When applicable, advise the individual/parent/carer when the subsequent dose is due. When administration is postponed advise the individual/parent/carer when to return for vaccination. Advise the individual/parent/carer of preventative measures to reduce exposure to hepatitis A including careful attention to food and water hygiene and scrupulous hand washing.
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Immunisation is recommended for MSM and they should also be informed about the risks of hepatitis A, and about the need to maintain high standards of personal hygiene during sex. 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. Hepatitis A vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis B, hepatitis C and hepatitis E viruses

Records	Record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Service (CHIS) using the appropriate documentation/pathway as required by any local or contractual arrangement. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	Product
	• Immunisation Against Infectious Disease: The Green Book Chapter 4, updated June 2012, Chapter 7, updated10 January 2020, and Chapter 17, updated 04 December 2013. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for AVAXIM®, Sanofi Pasteur. Last updated 14 April 2021 https://www.medicines.org.uk/emc/medicine/6206 • Summary of Product Characteristic for Havrix® Junior Monodose®, GlaxoSmithKline UK. Last updated 19 November 2020 https://www.medicines.org.uk/emc/medicine/2040 • Summary of Product Characteristic for Havrix® Monodose®, GlaxoSmithKline UK. Last updated 19 November 2020 https://www.medicines.org.uk/emc/medicine/2041 • Summary of Product Characteristic for VAQTA® Paediatric, MSD Ltd. Last updated 29 January 2021 https://www.medicines.org.uk/emc/product/1397/smpc • Summary of Product Characteristic for VAQTA® Adult, MSD Ltd. Last updated 29 January 2021 https://www.medicines.org.uk/emc/medicine/6210 • NaTHNaC recommendations for hepatitis A vaccination for travel. Accessed 20 September 2021 https://travelhealthpro.org.uk/disease/70/hepatitis-a • Public health control and management of hepatitis A guidance. Public Health England. Published June 2017 Updated 16 November 2018 https://www.gov.uk/government/publications/hepatitis-a-infection-prevention-and-control-guidance **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

Hepatitis A vaccine PGD v04.00 Valid from: 01/11/2021 Expiry: 31/10/2023

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Practitioner

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

PGDs 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 PGD 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 organisation** for the above named healthcare 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.