Public Health England

PHE publications gateway number: 2018521

PATIENT GROUP DIRECTION (PGD)

Administration of hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) to individuals requiring pre or post exposure protection against hepatitis A and/or hepatitis B virus during times of monovalent hepatitis vaccine supply shortages.

This PGD is for the administration of hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed) by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	HepA/B vaccine (Temp) PGD
Version no:	V02.00
Valid from:	01 November 2018
Review date:	01 May 2020
Expiry date:	31 October 2020

Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisation 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.

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-patient-group-direction-pgd

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

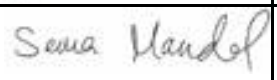
[1] This includes any relevant amendments to legislation (eg 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE HepA/B vaccine (Temp) PGD issued for use during times of monovalent hepatitis vaccine supply shortages.	12 October 2017
V02.00	HepA/B vaccine (Temp) PGD amended to: • include additional healthcare practitioners in Section 3 • refer to vaccine incident guidelines in off-label and storage sections • amended to reflect temporary recommendation updates and change in supply situation • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	28 September 2018

1. PGD development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist - Immunisation and Countermeasures, PHE		28/09/2018
Doctor	Sema Mandal Consultant Epidemiologist, Immunisation and Countermeasures, PHE		28/09/2018
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisation and Countermeasures, PHE		28/09/2018

This PGD 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)
Sema Mandal	Consultant Epidemiologist, Immunisation and Countermeasures, Public Health England
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England Lancashire and South Cumbria
Lesley McFarlane	Screening and Immunisation Co-ordinator, NHS England / Public Health England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
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
Sharon Webb	Programme Manager/Registered Midwife, NBHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Helen Wilkinson	Principal Pharmacist, Bristol, North Somerset & South Gloucestershire Clinical Commissioning Group

2. Organisational authorisations

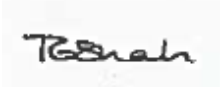
The PGD is not legally valid until it has had the relevant organisational authorisation.

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 London Region authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
This PGD must only be used by specified registered healthcare professionals working for providers that are directly commissioned by NHS England London Region, or who are administering vaccinations as part of a national immunisation programme, and who have been named and authorised to practice under it.
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Director of Nursing / Deputy Regional Chief Nurse NHS England (London Region)	**Jane Clegg**		**25/10/2018**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Director of Nursing (South London) NHS England London Region	**Gwen Kennedy**		**10/10/2018**
Pharmacy Advisor, NHS England London Region	**Tushar Shah**		**10/10/2018**

Local enquiries regarding the use of this PGD may be directed to england.londonimms@nhs.net

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 Public Health England and/or NHS England 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	In light of recent global shortages of hepatitis A and B vaccines that severely impacted UK supply, PHE issued temporary dose sparing advice to preserve and prioritise monovalent hepatitis vaccine stock for those with the greatest ability to benefit and highest immediate need. As supplies have overall improved for hepatitis A and hepatitis B vaccine, and vaccine is more widely available for all groups, these recommendations are no longer being followed. However, as the future supply situation is unclear, they remain on gov.uk. If PHE advises that the temporary recommendations should be followed for either hepatitis A or hepatitis B vaccination, HepA/B vaccine may be administered to individuals who only require one antigen where this is recommended in accordance with either: • PHE hepatitis A vaccination temporary recommendations or • PHE hepatitis B vaccination in adults and children: temporary recommendations
Criteria for inclusion Continued over page	**Use of HepA/B vaccine in accordance with PHE dose-sparing recommendations** PHE has issued temporary dose sparing advice to preserve and prioritise monovalent hepatitis vaccine stock for those with the greatest ability to benefit and highest immediate need (PHE hepatitis A vaccination temporary recommendations and PHE hepatitis B vaccination in adults and children: temporary recommendations). These recommendations include administration of HepA/B vaccine in some circumstances where the individual only requires one of the hepatitis antigens A or B. The age of the individual, clinical priority and availability of combined and monovalent vaccine alternatives should be considered. When PHE advises following the temporary recommendations, HepA/B vaccine may be administered in accordance with PHE dose-sparing recommendations to individuals meeting the criteria below. **Post-exposure** Individuals who: • are babies born to hepatitis B infected mothers • have been potentially exposed to hepatitis B infected blood or body fluids • have been potentially exposed to hepatitis A and who are recommended hepatitis A vaccine in accordance with Public health control and management of hepatitis A guidance **Pre-exposure** Individuals 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) • have chronic liver disease • are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure (CKD stage 4 or 5) that is likely to require haemodialysis or transplant • are haemophiliac or receive regular blood or blood products, or carers who administer such products • are at risk of hepatitis B and/or hepatitis A infection because of

Criteria for inclusion (continued)	their sexual behaviour, such as commercial sex workers or men who have sex with men (MSM), see Additional information section • are people who inject drugs (PWID) or those who are likely to progress to injecting (see "The Green Book" Chapter 18) • are sexual partners, children, or other close family or household contacts of people who inject drugs (PWID) • are household, close family or sexual contacts of an individual with hepatitis B infection • are members of a family adopting children from countries with a high or intermediate prevalence of hepatitis B • are, or who are close family or household members of, short-term foster carers who receive emergency placements • are, or who are close family or household members of, permanent foster carers who accept a child known to be hepatitis B infected • are inmates of custodial institutions in the UK, including those on remand • are resident in accommodation for those with learning disabilities or other large residential institution where standards of personal hygiene may be poor • are adults or children attending day care, schools and centres for those with learning disabilities and, based on local risk assessment, are at risk of frequent percutaneous exposure (eg biting or being bitten) • are recommended hepatitis A vaccine in accordance with Public health control and management of hepatitis A guidance to interrupt tertiary transmission in an outbreak/incident setting
Criteria for exclusion[2]	Individuals for whom no valid consent has been received. Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of hepatitis A or hepatitis B vaccine or to any component of the vaccine (including trace components from the manufacturing process such as neomycin) • are at increased risk of hepatitis A or hepatitis B infection solely because of their occupation • require solely hepatitis B vaccination for the purpose of travel • 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	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. 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.

[2] 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

Action to be taken if the patient is excluded	Individuals who have had a confirmed anaphylactic reaction to a previous dose of hepatitis A or hepatitis B containing 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 and/or B exposure should be referred to their employer's occupational health provider for vaccination. Individuals requiring solely hepatitis B vaccination for overseas travel purposes should be administered hepatitis B in accordance with local policy. However, hepatitis B vaccination for travel is not remunerated by the NHS as part of additional services and is therefore not covered by this PGD unless hepatitis A vaccination is also indicated. 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. In a GP practice setting, 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. 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. In a GP practice setting, inform or refer to the GP or prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength & formulation of drug	Hepatitis A virus (inactivated) and hepatitis B recombinant DNA (rDNA) (HepA/B) vaccine (adsorbed) eg: • Twinrix® Adult, suspension for injection in a pre-filled syringe or vial, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20 micrograms • Twinrix® Paediatric, suspension for injection in a pre-filled syringe or vial, hepatitis A virus (inactivated) 360 ELISA units and hepatitis B surface antigen 10 micrograms • Ambirix®, suspension for injection in a pre-filled syringe, hepatitis A virus (inactivated) 720 ELISA units and hepatitis B surface antigen 20 micrograms An appropriate vaccine product should be selected considering the age of the individual, clinical priority and availability of combined and monovalent vaccine alternatives, see Dose and frequency of administration section, PHE hepatitis A vaccination temporary recommendations and PHE hepatitis B vaccination in adults and children: temporary recommendations.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	Ambirix® and Twinrix® Paediatric are licensed for children and adolescents from 1 year up to and including 15 years of age. Twinrix® Adult is licensed for adults and adolescents 16 years of age and above. During vaccine supply shortages it may be appropriate to provide combined HepA/B vaccine off-label from birth (administered into the anterolateral aspect of the thigh), to provide adults the vaccine licensed for children, to provide infants/children/adolescents the vaccine licensed for adults or to provide simultaneous vaccine doses to provide the required total dose. Such off-label administration may be undertaken under this PGD where it is in accordance with PHE hepatitis A vaccination temporary recommendations and/or PHE hepatitis B vaccination in adults and children: temporary recommendations. The age of the individual, clinical priority and availability of combined and monovalent vaccine alternatives should be considered. Please refer to the most up to date guidance as appropriate from PHE. 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. 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. The deltoid region of the upper arm may be used in individuals over one year of age. The anterolateral aspect of the thigh is the preferred route for infants

<table>
<tr><td>Route / method of administration
(continued)</td><td>under one year old (Off-label use).

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 given at least 2.5cm apart. The site at which each was given should be noted in the individual's records.

Where, in accordance with PHE hepatitis A vaccination temporary recommendations, the required hepatitis A vaccine dose is provided as two simultaneous doses of HepA/B vaccine, these should be administered simultaneously at the same site.

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" Chapter 4). However, this route of administration may result in suboptimal immune response to the vaccine.

The suspension for injection may sediment during storage to leave a fine white deposit with a clear colourless layer. Shake the vaccine well before administration to obtain a uniform turbid 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 HepA/B vaccines contain different concentrations of antigen (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 manufacturers SPC. During times of hepatitis vaccine supply shortages, off-label administration may be appropriate in accordance with PHE hepatitis A vaccination temporary recommendations and/or PHE hepatitis B vaccination in adults and children: temporary recommendations.

<table>
<tr><th>Vaccine</th><th>Age (licenced use)</th><th>Dose HepA*</th><th>Dose HepB</th><th>Volume</th></tr>
<tr><td>Twinrix® Adult</td><td>16 years or over</td><td>720 ELISA units</td><td>20 micrograms</td><td>1.0ml</td></tr>
<tr><td>Twinrix® Paediatric*</td><td>One to 15 years</td><td>360 ELISA units</td><td>10 micrograms</td><td>0.5ml</td></tr>
<tr><td>Ambirix®</td><td>One to 15 years</td><td>720 ELISA units</td><td>20 micrograms</td><td>1.0ml</td></tr>
<tr><td colspan="5">*During times of vaccine shortage it may be necessary to use two simultaneous doses of HepA/B vaccine to provide a full or half-dose of hepatitis A antigen in accordance with PHE hepatitis A vaccination temporary recommendations. A full dose of hepatitis A</td></tr>
</table>
</td></tr>
</table>

Dose and frequency of administration (continued)	antigen for adults and children respectively are 1440 ELISA units and 720 ELISA units. Where applicable HepA/B vaccine may be used interchangeably with monovalent vaccine, as supplies become available, to complete a vaccine course. **Licensed dose to provide Hepatitis A and B protection** Twinrix® Adult: 1ml administered at 0, 1 and 6 months**. Twinrix® Paediatric: 0.5ml administered at 0, 1 and 6 months** Ambirix®: 1ml administered at 0 and 6-12 months** **where 0 is the elected start date of the course Avoid using 0, 7, 21 day (super-accelerated) schedule which is wasteful during times of vaccine supply shortages. This is because the immune response following 3 doses with the super accelerated schedule is lower than that with the standard or accelerated schedules and deferral of the reinforcing/booster dose at 12 months is more risky. 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 hepatitis A vaccine, the vaccine may provide some protection before antibodies can be detected using current assays. **Use of HepA/B vaccine in accordance with PHE dose-sparing recommendations** If there is a need to use HepA/B vaccine post-exposure in place of monovalent vaccine due to supply shortages the following schedules may be appropriate. **Post-exposure to hepatitis B**, recommendations in Table 18.7 of Chapter 18 of "The Green Book" should be followed to complete vaccination status or provide a booster where required. For unvaccinated individuals an accelerated course at 0, 1, and 2 months is recommended where protection is required (see PHE hepatitis B vaccination in adults and children: temporary recommendations). **Post-exposure to hepatitis A**, a single dose, which may be provided by one or two simultaneous HepA/B vaccines to provide adequate antigen, depending on the individual's age, immune status and vaccine used, see PHE hepatitis A vaccination temporary recommendations and Public health control and management of hepatitis A). **For pre-exposure hepatitis B** vaccination during times of vaccine shortage preferably use the 0, 1, 6*** months schedule or, if rapid protection is required, the accelerated schedule of 0, 1, 2 months. ***In healthy adults and children, a high proportion will have started to respond after a second dose of hepatitis B vaccine and a completing dose given after an exposure should provide rapid protection. Therefore PHE hepatitis B vaccination in adults and children: temporary recommendations advise deferring the third dose of primary pre-exposure hepatitis B immunisation to at least 6 months in those not at immediate risk of exposure who can recognise exposure and access care promptly.

Continued over page

Dose and frequency of administration (continued)	**For pre-exposure hepatitis A** vaccination a single dose of hepatitis A containing vaccine should be provided. When HepA/B vaccine is used in place of monovalent hepatitis A vaccine the lower hepatitis A antigen content of the combined product should be noted. It may be necessary in some instances to provide two simultaneous HepA/B vaccines at the same site to provide the required hepatitis A antigen dose (see PHE hepatitis A vaccination temporary recommendations). **Hepatitis A Booster** In order to provide long-term protection against hepatitis A, a single reinforcing dose is ordinarily recommended 6 to 12 months after the first dose. When hepatitis A vaccine is in short supply, delayed boosting should be considered for individuals primed with a full hepatitis A antigen dose. Boosting can be delayed for up to 5 years in most situations. Individuals who have been primed with half the licensed antigen dose for monovalent hepatitis A vaccine should be considered for boosting after 1 year. In those in whom hepatitis A priming may not have been optimal, e.g. 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 PHE hepatitis A vaccination temporary recommendations). **Hepatitis B Booster** To protect against hepatitis B individuals receiving a schedule of hepatitis B containing vaccine at 0, 1, and 2 months would ordinarily be recommended a booster at 12 months. During times of vaccine shortage this may be deferred to 24 months in immunocompetent individuals.
Duration of treatment	Dependent on vaccine schedule, see Dose and frequency of administration.
Quantity to be supplied / administered	Dose of 0.5ml to 2.0ml per an administration depending on the age of the individual and vaccine product used, see Dose and frequency of administration.
Supplies	HepA/B vaccine is not usually centrally supplied and should be obtained directly from manufacturers/wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and 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. 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.
Disposal Continued over page	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of

Disposal (continued)	safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations 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. Vaccine is recommended even if 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 & management of adverse reactions	Adverse reactions to hepatitis vaccines are usually mild and confined to the first few days after immunisation. The most common reactions are mild, transient pain, redness and swelling at the injection site. Other commonly reported reactions to hepatitis A vaccination include other injection site reactions (haematoma, pruritus, bruising), general symptoms such as fever, malaise, fatigue, irritability, drowsiness, headache, and gastrointestinal symptoms including nausea, diarrhoea and loss of appetite. 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 at: http://yellowcard.mhra.gov.uk 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. Immunisation promotional material and patient advice leaflets may be provided as appropriate: • What to do if you have to wait for a dose of hepatitis B vaccine: advice for patients Available from: www.gov.uk/government/collections/immunisation
Patient advice / follow up treatment Continued over page	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 individuals administered the vaccine subcutaneously that this route of administration may result in suboptimal immune response to

Patient advice / follow up treatment (continued)	the vaccine. Advise individual of preventative measures to reduce exposure to hepatitis A (ie careful attention to food and water hygiene and scrupulous hand washing, further details can be found on www.nhs.uk) and preventative measures to reduce exposure to hepatitis B (ie avoiding exposure to blood and bodily fluids, further details can be found on www.nhs.uk). Sexual contacts of individuals infected with hepatitis B should be advised regarding the appropriate use of condoms; a reasonable level of protection can be assumed following the second dose, provided that completion of the schedule can be assured.
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. The PHE hepatitis A vaccination temporary recommendations and PHE hepatitis B vaccination in adults and children: temporary recommendations provide dose-sparing options for hepatitis A and hepatitis B vaccine selection, along with additional information and rationale. They should inform selection of which hepatitis A and/or hepatitis B containing vaccine to administer during vaccine shortages affecting UK supply. HepA/B vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis C and hepatitis E viruses. There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since HepA/B 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.
Records	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • 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 Patient Group Direction (PGD) Records should be signed and dated (or a password controlled immunisers record on e-records). All records should be clear, legible and contemporaneous. The local Child Health Information Services team (Child Health Records Department) must be notified 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, last updated June 2012, Chapter 7, last updated October 2016, Chapter 17, last updated December 2013 and Chapter 18, last updated June 2017. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Twinrix® Adult, GlaxoSmithKline UK. Last updated 24 November 2016. https://www.medicines.org.uk/emc/medicine/2061 • Summary of Product Characteristic for Twinrix® Paediatric, GlaxoSmithKline UK. Last updated 24 November 2016. https://www.medicines.org.uk/emc/medicine/2062 • Summary of Product Characteristic for Ambirix®, GlaxoSmithKline UK. Last updated 23 November 2016. https://www.medicines.org.uk/emc/medicine/20491 • NaTHNaC resources. Accessed 10 August 2017. https://travelhealthpro.org.uk/countries • Hepatitis A infection: prevention and control guidance including PHE hepatitis A vaccination temporary recommendations and Public health control and management of hepatitis A guidance. Public Health England. Last updated 19 July 2018. https://www.gov.uk/government/publications/hepatitis-a-infection-prevention-and-control-guidance • Hepatitis B: vaccine recommendations during supply constraints including Plan for phased re-introduction of hepatitis B vaccine for lower priority groups 2018, last updated February 2018, PHE hepatitis B vaccination in adults and children: temporary recommendations, last updated 21 August 2017 and What to do if you have to wait for a dose of hepatitis B vaccine: advice for patients, last updated 7 August 2017. Landing page last updated 12 July 2018. https://www.gov.uk/government/publications/hepatitis-b-vaccine-recommendations-during-supply-constraints **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • 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. January 2014. https://www.nice.org.uk/guidance/mpg2/resources • PHE Immunisation Collection

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Key references (continued)	https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

7. Practitioner authorisation sheet

HepA/B vaccine (Temp) PGD v02.00 Valid from: 01/11/2018 Expiry: 31/10/2020

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 the following organisation ……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.