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## PATIENT GROUP DIRECTION (PGD)

Administration of combined hepatitis A virus (inactivated) and typhoid polysaccharide vaccine to individuals considered at risk of exposure to *Salmonella enterica serovar typhi*, (*S. typhi*) and/or hepatitis A virus, in accordance with recommendations from the National Travel Health Network and Centre (NaTHNaC) or in accordance with PHE hepatitis A temporary recommendations.

This PGD is for the administration of combined hepatitis A virus (inactivated) and typhoid polysaccharide (HepA/Typhoid) vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no: HepA/Typhoid vaccine PGD  
Version no: V01.00  
Valid from: 01 March 2018  
Review date: 01 September 2019  
Expiry date: 29 February 2020

**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>1</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)


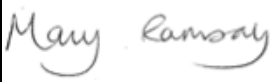

<sup>1</sup> This includes any relevant amendments to legislation (eg [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).

## Change history

Version number	Change details	Date
V01.00	New PHE HepA/Typhoid vaccine PGD	18 January 2018

## 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		01/02/2018
<b>Doctor</b>	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		01/02/2018
<b>Registered Nurse</b> (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		01/02/2018

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
Dipti Patel	NaTHNaC Director, Public Health England
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
Sharon Webb	Programme Manager - IDPS , NHS Screening Programmes, Public Health England (Midwife)

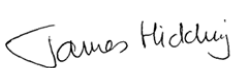
## 2. Organisational authorisations



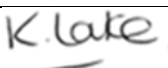
The PGD is not legally valid until it has had the relevant organisational authorisation.

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 (East)** authorises this PGD for use by the services or providers listed below:

<b>Authorised for use by the following organisations and/or services</b>
All NHS England Midlands and East (East) commissioned immunisation services or NHS Trusts providing immunisation services covering Norfolk, Suffolk, Cambridgeshire, Peterborough, Essex, Southend-on-Sea and Thurrock local authorities, Health and Justice facilities where the East DCO is the commissioner
<b>Limitations to authorisation</b>
None

<b>Organisational approval (legal requirement)</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
<b>Deputy Medical Director</b>	<b>Dr. James Hickling</b>		<b>27.02.2018</b>

<b>Additional signatories according to locally agreed policy</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
<b>Screening and Immunisation Lead</b>	<b>Dr. Pam Hall</b>		<b>27.02.2018</b>
<b>Pharmacist</b>	<b>Paul Duell</b>		<b>27.02.2018</b>
<b>Screening and Immunisation Coordinator</b>	<b>Dr. Karen Lake</b>		<b>27.02.2018</b>

Local enquiries regarding the use of this PGD may be directed to  
 For East Anglia email: [England.ea-phsi@nhs.net](mailto:England.ea-phsi@nhs.net)  
 For Essex email: [england.essexatimms@nhs.net](mailto:england.essexatimms@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

<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 and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>• paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below.</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>
<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 PGD 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 PGDs)</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</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 PGD 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 <i>S. typhi</i>, and hepatitis A virus in accordance with national recommendations including:</p> <ul style="list-style-type: none"> <li>• <a href="#">Chapter 7</a>, <a href="#">Chapter 17</a> and <a href="#">Chapter 33</a> of Immunisation Against Infectious Disease: “The Green Book”</li> <li>• <a href="#">NaTHNaC</a> recommendations for hepatitis A and typhoid vaccination for travel</li> </ul> <p>In light of the shortage of global hepatitis vaccine that has severely impacted UK supply, 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. Whilst these temporary recommendations are in effect, HepA/Typhoid vaccine may be administered to individuals who only require hepatitis A vaccination where such use is in accordance with either:</p> <ul style="list-style-type: none"> <li>• <a href="#">PHE Hepatitis A vaccination in adults - temporary recommendations</a></li> </ul> <p>Or</p> <ul style="list-style-type: none"> <li>• <a href="#">PHE Hepatitis A vaccination in children - temporary recommendations</a></li> </ul>		
<p><b>Criteria for inclusion</b></p>	<p>Individuals from 16 years of age requiring hepatitis A and typhoid pre-exposure prophylaxis who:</p> <ul style="list-style-type: none"> <li>• intend to travel, where typhoid vaccination is currently recommended for travel by NaTHNaC (see the <a href="#">Travel Health Pro</a> website for country-specific advice on typhoid vaccination) and for whom hepatitis A vaccination is also currently indicated (see <a href="#">Indications for hepatitis A vaccination</a> below).</li> </ul> <p>During vaccine supply shortages, adults and children who require hepatitis A vaccination (see <a href="#">Indications for hepatitis A vaccination</a> below) where use of HepA/Typhoid vaccine is recommended in accordance with <a href="#">PHE hepatitis A vaccination temporary recommendations</a>.</p> <table border="1" data-bbox="550 1411 1444 2049"> <thead> <tr> <th data-bbox="550 1411 1444 1444"><b>Indications for Hepatitis A vaccination</b></th> </tr> </thead> <tbody> <tr> <td data-bbox="550 1444 1444 2049"> <p>Adults and children from 1 year of age who:</p> <ul style="list-style-type: none"> <li>• intend to travel, where hepatitis A vaccination is currently recommended for travel by <a href="#">NaTHNaC</a> (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>And adults and children from 2 months of age (see <a href="#">Special Considerations</a>) 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> </td> </tr> </tbody> </table>	<b>Indications for Hepatitis A vaccination</b>	<p>Adults and children from 1 year of age who:</p> <ul style="list-style-type: none"> <li>• intend to travel, where hepatitis A vaccination is currently recommended for travel by <a href="#">NaTHNaC</a> (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>And adults and children from 2 months of age (see <a href="#">Special Considerations</a>) 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>
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<p><b>Criteria for exclusion<sup>2</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>• have had a confirmed anaphylactic reaction to a previous dose of hepatitis A vaccine, typhoid Vi polysaccharide vaccine or to any component of the HepA/Typhoid vaccine (including trace components from the manufacturing process which may include neomycin, see SPCs)</li> <li>• are at increased risk of <i>S. typhi</i> or hepatitis A infection because of their occupation</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>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>Infants who receive HepA/Typhoid in accordance with PHE temporary recommendations may not be provided protection from the typhoid component (see <a href="#">Special Considerations</a>).</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 who have had a confirmed anaphylactic reaction to a previous dose of hepatitis A vaccine, typhoid Vi polysaccharide 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 typhoid and/or 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>

<sup>2</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>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

<b>Name, strength &amp; formulation of drug</b>	<p>Hepatitis A (inactivated, adsorbed) and typhoid Vi polysaccharide vaccine eg:</p> <ul style="list-style-type: none"> <li>• ViATIM<sup>®</sup> vaccine, 0.5ml hepatitis A virus, (GBM strain) 160 U* (inactivated, adsorbed) and 0.5ml <i>S. typhi</i> (Ty2 strain) capsular Vi polysaccharide 25 micrograms, suspension for injection in a 1ml dual-chamber pre-filled syringe</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>
<b>Legal category</b>	<p>Prescription only medicine (POM)</p>
<b>Black triangle▼</b>	<p>No</p>
<b>Off-label use</b>	<p>ViATIM<sup>®</sup> administration to individuals under 16 years of age is off-label. During vaccine supply shortages it may be appropriate to provide adults and children requiring hepatitis A vaccine with HepA/Typhoid off-label 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>. Please refer to the most up to date guidance as appropriate from PHE.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage section</a> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">PHE Vaccine Incident Guidance</a>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</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>
<b>Route / method of administration</b>	<p>Administer by intramuscular injection into the deltoid region of the upper arm. 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 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>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 two vaccine components should only be mixed immediately prior to injection. The inactivated hepatitis A vaccine (closest to the plunger) is a cloudy white suspension and the typhoid Vi polysaccharide vaccine (closest to the needle) is a clear colourless solution. Shake before mixing and again prior to injection to obtain a</p>

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<p><b>Route / method of administration</b> (continued)</p>	<p>homogenous cloudy whitish suspension. The contents of the two chambers are mixed by slowly advancing the plunger.</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><b>Primary vaccination</b></p> <p>Single 1ml dose.</p> <p>The full 1ml dose should be administered to children when indicated during times of vaccine supply shortages (see <a href="#">Off-label</a> section).</p> <p>The vaccine should be given at least two weeks prior to risk of exposure to <i>S. typhi</i> or hepatitis A virus. Based on individual risk assessment, vaccination may be considered up until departure but protection may be limited.</p> <p><b>Typhoid revaccination</b></p> <p>Individuals who plan to travel to an area where typhoid vaccination is currently recommended for travel by <a href="#">NaTHNaC</a>, and who have not received typhoid vaccine in the preceding 3 years should be re-vaccinated against <i>S. typhi</i>.</p> <p>Individuals who remain at risk of exposure to <i>S. typhi</i> should be revaccinated every three years (see <a href="#">Special Considerations</a> section).</p> <p>Note: Typhoid Vi polysaccharide containing vaccine may be used for revaccination when individuals have received non-Vi typhoid vaccine for the preceding dose.</p> <p><b>Hepatitis A booster vaccination</b></p> <p>For those who require long-term, or subsequent, protection against infection caused by hepatitis A virus, a single reinforcing dose of hepatitis A containing vaccine 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 of hepatitis A.</p>

<b>Duration of treatment</b>	<p>Single dose.</p> <p>Typhoid revaccination and/or a hepatitis A booster may be indicated for individuals who remain at risk of typhoid fever and/or hepatitis A respectively (see <a href="#">Dose and frequency of administration</a>).</p>
<b>Quantity to be supplied / administered</b>	<p>Single 1.0ml dose per an administration.</p>
<b>Supplies</b>	<p>HepA/Typhoid vaccine is not centrally supplied and should be obtained directly from manufacturers/wholesalers.</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>
<b>Storage</b>	<p>Store between +2°C to +8°C.</p> <p>Store in original packaging in order to protect from light.</p> <p>Do not freeze.</p> <p>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 <a href="#">PHE Vaccine Incident Guidance</a>.</p>
<b>Disposal</b>	<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>
<b>Drug interactions</b>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.</p> <p>May be given at the same time as other vaccines.</p> <p>The effect of concomitant administration of immunoglobulins on the immunogenicity of the vaccine has not been assessed.</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>
<b>Identification &amp; management of adverse reactions</b>	<p>Adverse reactions to HepA/Typhoid vaccines are usually mild and transient. The most common are local reactions including pain, swelling, 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 include general symptoms such as fever, malaise, asthenia, itching, headache, general aches and pains, 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</p>
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<b>Identification &amp; management of adverse reactions</b> (continued)	available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>
<b>Reporting procedure of adverse reactions</b>	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 on: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a>  Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
<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>The individual/parent/carer should be advised that hepatitis A vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis B, C and hepatitis E viruses.</p> <p>The individual/parent/carer should be advised that typhoid Vi polysaccharide vaccine offers protection against typhoid fever caused by <i>S. typhi</i>, it does not prevent paratyphoid fever or infection with any other serotypes of <i>S. enterica</i>.</p> <p>The individual/parent/carer should be advised that protection against <i>S. typhi</i> by vaccination may be less if a large number of infective organisms are ingested. Because of the limited protection offered by the vaccine, the importance of scrupulous attention to personal, food and water hygiene must still be emphasised for those travelling to endemic areas.</p> <p>When applicable, advise parent/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 virus and <i>S. typhi</i> including careful attention to food and water hygiene and scrupulous hand washing.</p>
<b>Special considerations / additional information</b>  Continued over page	<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</p>

<p><b>Special considerations / additional information</b> (continued)</p>	<p>selection of which hepatitis A containing vaccine to administer whilst vaccine shortage affects UK supply.</p> <p>Protective antibody titres to typhoid Vi antigen fall over time. Re-vaccination against <i>S. typhi</i> is necessary when continuing protection is required. Additional doses of Vi vaccine do not boost serum antibody levels; re-vaccination returns antibody levels to those achieved after the primary immunisation.</p> <p>Non-conjugated polysaccharide vaccines are poorly immunogenic in infants and young children. There is little definitive data on the efficacy of Vi vaccine in children aged less than 18 months.</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 and typhoid polysaccharide vaccine is an inactivated (subunit) vaccine, the risks to the foetus are negligible and vaccine should be given where there is a definite risk of infection.</p> <p>Local Health Protection Team (HPT) should be informed immediately whenever a patient is suspected of having typhoid fever. Typhoid vaccine is not recommended for close contacts of either cases or carriers, or during an outbreak of typhoid fever in the UK. Both cases and carriers of <i>S. typhi</i> should be advised to be scrupulous in their hygiene practices. Carriers should be referred for specialist clinical management.</p>
<p><b>Records</b></p>	<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>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>

## 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, <a href="#">Chapter 17</a>, last updated 04 December 2013, and <a href="#">Chapter 33</a>, last updated 28 August 2015. <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 ViATIM<sup>®</sup>, Sanofi Pasteur. Last updated 15 March 2017. <a href="http://www.medicines.org.uk/emc/medicine/7684">http://www.medicines.org.uk/emc/medicine/7684</a></li><li>• National Travel Health Network and Centre (<a href="#">NaTHNaC</a>). Accessed 18 January 2018. <a href="https://travelhealthpro.org.uk/factsheet/21/hepatitis-a">https://travelhealthpro.org.uk/factsheet/21/hepatitis-a</a> <a href="https://travelhealthpro.org.uk/factsheet/49/typhoid-and-paratyphoid">https://travelhealthpro.org.uk/factsheet/49/typhoid-and-paratyphoid</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 14 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>• 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://bnf.nice.org.uk/drug/hepatitis-a-with-typhoid-vaccine.html">https://bnf.nice.org.uk/drug/hepatitis-a-with-typhoid-vaccine.html</a> <a href="https://bnfc.nice.org.uk/drug/hepatitis-a-with-typhoid-vaccine.html">https://bnfc.nice.org.uk/drug/hepatitis-a-with-typhoid-vaccine.html</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><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-005336">https://www.rcn.org.uk/professional-development/publications/pub-005336</a></li><li>• National Minimum Standards for Immunisation Training <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>• PHE Immunisation Collection <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• PHE Vaccine Incident Guidance <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li><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></ul>
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## 7. Practitioner authorisation sheet

**HepA/Typhoid vaccine PGD v01.00 Valid from: 01/03/2018 Expiry: 29/02/2020**

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 **INSERT NAME OF 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.