UK Health Security Agency

NHS

Publications gateway number: GOV-11415

Combined Hepatitis A Virus (Inactivated) and Typhoid Polysaccharide Vaccine Patient Group Direction (PGD)

This PGD is for the administration of combined hepatitis A virus (inactivated) and typhoid polysaccharide vaccine (HepA/Typhoid) to individuals considered at risk of exposure to *Salmonella enterica serovar typhi*, (*S. typhi*) and hepatitis A virus in accordance with recommendations from the National Travel Health Network and Centre (NaTHNaC).

This PGD is for the administration of HepA/Typhoid 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:	V03.00
Valid from:	01 March 2022
Review date:	01 September 2023
Expiry date:	29 February 2024

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 UKHSA PGD templates for authorisation can be found from: Immunisation patient group direction (PGD) templates

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: england.londonimms@nhs.net

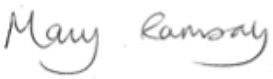
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE HepA/Typhoid vaccine PGD	18/01/2018
V02.00	PHE HepA/Typhoid vaccine PGD reviewed and amended to: • remove inclusion criteria for administration during vaccine supply shortages in accordance with PHE Hepatitis A temporary recommendations • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	28/11/2019
V03.00	HepA/Typhoid vaccine PGD was reviewed and amended to: • update organisation from PHE to UKHSA • update references • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs	16/02/2022

1. PGD development

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		16/02/2022
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		18/02/2022
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		16/02/2022

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Management Group and the UKHSA Clinical Quality and Oversight 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
Michael Gregory	Medical Director for Commissioning, NHS England and NHS Improvement (North West)
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA
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 West)
Sema Mandal	Medical Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
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)
Dipti Patel	NaTHNaC Director, UKHSA
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)

2. Organisational authorisations

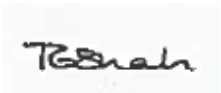
The PGD is not legally valid until it has had the relevant organisational authorisation.

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.

NHS England and NHS Improvement 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 and NHS Improvement 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**
Chief Nurse, NHS England and NHS Improvement London Region	Jane Clegg		28/02/2022

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Director of Nursing Leadership and Quality, NHS England and NHS Improvement London Region	Gwen Kennedy		25/02/2022
Lead Pharmacy Advisor, NHS England and NHS Improvement London Region	Tushar Shah		24/02/2022

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 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 *S. typhi,* and hepatitis A virus in accordance with national recommendations including: • Chapter 17 and Chapter 33 of Immunisation Against Infectious Disease: the 'Green Book' • NaTHNaC recommendations for hepatitis A and typhoid vaccination for travel
Criteria for inclusion	Individuals from 16 years of age requiring hepatitis A and typhoid vaccine who intend to travel, where typhoid and hepatitis A vaccination is currently recommended for travel by NaTHNaC (see the Travel Health Pro website for country-specific advice).
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 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 SPC) • are at increased risk of *S. typhi* or 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	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.
Action to be taken if the patient is excluded Continued over page	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. 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. 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

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

Action to be taken if the patient is excluded continued	account. The importance of scrupulous attention to personal, food and water hygiene must be emphasized. 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. Advise the individual/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, adsorbed) and typhoid Vi polysaccharide vaccine: • ViATIM® vaccine, 0.5ml hepatitis A virus, (GBM strain) 160 U* (inactivated, adsorbed) and 0.5ml *S. typhi* (Ty2 strain) capsular Vi polysaccharide 25 micrograms, suspension for injection in a 1ml dual-chamber pre-filled syringe *In the absence of an international standardised reference, the antigen content is expressed using an in-house method of the manufacturer.
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	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 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/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration	Administer by intramuscular injection into the deltoid region of the upper arm. 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. For individuals with a bleeding disorder, vaccines normally given by the intramuscular route should be given in accordance with the recommendations in the 'Green Book' Chapter 4. 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 homogenous cloudy whitish suspension. The contents of the two chambers are mixed by slowly advancing the plunger. 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

Dose and frequency of administration	**Primary vaccination** Single 1ml dose. The vaccine should be given at least two weeks prior to risk of exposure to *S. typhi* or hepatitis A virus. Based on individual risk assessment, vaccination may be considered up until departure but protection may be limited. **Typhoid revaccination** Individuals who plan to travel to an area where typhoid vaccination is currently recommended for travel by NaTHNaC, and who have not received typhoid vaccine in the preceding 3 years should be re-vaccinated against *S. typhi*. Individuals who remain at risk of exposure to *S. typhi* should be revaccinated every three years (see Special Considerations section). Note: Typhoid Vi polysaccharide containing vaccine may be used for revaccination when individuals have received non-Vi typhoid vaccine for the preceding dose. **Hepatitis A booster vaccination** 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. 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.
Duration of treatment	Single dose. 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 Dose and frequency of administration).
Quantity to be supplied / administered	Single 1.0ml dose per an administration.
Supplies	HepA/Typhoid vaccine is not 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 Chapter 3).
Storage	Store 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 Vaccine Incident Guidance.
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. The effect of concomitant administration of immunoglobulins on the immunogenicity of the vaccine has not been assessed. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website.
Identification and management of adverse reactions	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. 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. 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.
Reporting procedure of adverse reactions	Healthcare professionals and individuals/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/carer of possible side effects and their management. The individual/carer should be advised to seek medical advice in the event of an adverse reaction. The individual/carer should be advised that hepatits A vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis B, C and hepatitis E viruses. The individual/carer should be advised that typhoid Vi polysaccharide vaccine offers protection against typhoid fever caused by *S. typhi*, it does not prevent paratyphoid fever or infection with any other serotypes of *S. enterica*. The individual/carer should be advised that protection against *S. typhi* by vaccination may be less if a large number of infective organisms are ingested. The importance of scrupulous attention to personal, food and water hygiene must be emphasised for those travelling to endemic areas. When applicable, advise individual/carer when the subsequent dose is due. When administration is postponed advise the individual/carer when to return for vaccination.

Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. Protective antibody titres to typhoid Vi antigen fall over time. Re-vaccination against *S. typhi* 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. 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 an identified 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 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 Systems team (Child Health Records Department) 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 17, last updated 04 December 2013, and Chapter 33, last updated 3 April 2020. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for ViATIM®, Sanofi Pasteur. Last updated 26 February 2021. http://www.medicines.org.uk/emc/medicine/7684 • Factsheet: Typhoid and paratyphoid. NaTHNaC. Last Updated 27 January 2022. Accessed 3 February 2022. https://travelhealthpro.org.uk/factsheet/49/typhoid-and-paratyphoid https://travelhealthpro.org.uk/countries **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 • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

HepA/Typhoid vaccine PGD v03.00 Valid from: 01/03/2022 Expiry: 29/02/2024

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 the following named 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.