NHS Grampian | NHS Highland | NHS Orkney | NHS Shetland | NHS Tayside | NHS Eileanan Siar Western Isles

Patient Group Direction For The Administration Of Combined Hepatitis A and Typhoid Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/HepA_Typhoid/ MGPG1187	**Review Date:** November 2023 **Expiry Date:** November 2024	**Date Approved:** November 2021

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NHSG/PGD/hepA_typhoid/MGPG948, Version 1.1	
Date of change	**Summary of Changes**	**Section heading**
August 2021	NHS Highland, NHS Tayside and NHS Western Isles added to existing NoS PGD at point of review.	

NoS Identifier: NoS/PGD/HepA_Typhoid/MGPG1187
Keyword(s): PGD Patient Group Direction hepatitis A, typhoid, combined vaccine, community pharmacists

Policy Statement: It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	August 2021
	Completed:	October 2021
	Approved:	November 2021 (published – December 2021)
	Amended and reauthorised:	

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Diana Webster **Health Board:** NHSG **Title:** Public Health Consultant **Contact email:** diana.webster@nhs.scot **Signature:** .....DWebster..... **Date:** 20/12/2021
Senior representative of the professional group who will provide care under the direction	**Name:** John Fowlie **Health Board:** NHSG **Title:** Community Pharmacist **Contact email:** john.fowlie2@nhs.scot **Signature:** ..... **Date signed:** 14/12/2021
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** france.adamson@nhs.scot **Signature:** .....F Adamson..... **Date signed:** 07/12/2021
Pharmacist	**Name:** Liam Callaghan **Health Board:** NHSWI **Title :** Chief Pharmacist **Contact email:** liam.callaghan@nhs.scot **Signature:** ..... **Date signed:** 13/12/2021

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		24/11/2021

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		20/12/2021

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Liam Callaghan	**Pharmacist:** Chief Pharmacist NHSWI
Dr Diana Webster	**Medical Practitioner:** Public Health Consultant NHSG
John Fowlie	**Senior Representative:** Community Pharmacist NHSG
Sarah Buchan	Pharmaceutical Care Services Manager NHSG
Jackie Agnew	Head of Community Pharmacy NHSH
Andrew Radley	Consultant in Public Health Pharmacy NHST
Russell Mackay	Systems Lead Pharmacist NHSO
Mary McFarlane	Principal Pharmacist NHSS

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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer hepatitis A and typhoid vaccine for immunisation against typhoid fever and hepatitis A virus infection in adults and children over 16 years of age. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book, TRAVAX, NaTHNaC and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	• Those aged 16 years or older requiring (ViATIM®) where both typhoid and hepatitis A are required to be given at the same time. • Travellers to countries where typhoid is endemic (e.g. South Asia, parts of South-East Asia, the Middle East, Central and South America, and Africa), especially if staying with or visiting the local population. • Travellers to endemic areas (see above) with frequent and/or prolonged exposure to conditions where sanitation and food hygiene are likely to be poor. • Laboratory personnel who may handle *Salmonella typhi* in the course of their work. • Estates staff following risk assessment. • In special circumstances in a population as defined by the Health Protection Team. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals: • With current acute systemic or febrile illness • Who have had an anaphylactic reaction to previous dose of the vaccine or to any of its excipients • Individuals under the age of 16 years • Have had a known anaphylactic reaction to any of the excipients. **Note:** Vaccine may contain neomycin • Have a confirmed anaphylactic reaction to a previous dose of the vaccine

	• Pregnant or breastfeeding woman • Where there is no valid consent.
Precautions and special warnings	Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. In individuals with an impaired immune system, adequate antibody titres may not be obtained after a single dose of combined hepatitis A and typhoid vaccine. Such individuals may therefore require administration of additional doses. If possible, vaccination should be delayed until the completion of any immunosuppressive treatment. Individuals with chronic immunodeficiency such as HIV infection may be vaccinated if the underlying immunodeficiency allows the induction of an antibody response, even if limited. Individuals with a Bleeding Disorder - An individual risk assessment should be undertaken prior to vaccination. As with any intramuscular (IM) vaccination, the injection should be given with caution to individuals with thrombocytopenia or any coagulation disorder, as bleeding may occur following IM administration. Therefore, individuals with known bleeding disorders or taking anticoagulant therapy should receive the vaccine by deep subcutaneous injection route to reduce the risk of bleeding. Individuals should be informed of the risk of developing haematoma and what to do if this occurs.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. If clarification is required about an individual meeting the exclusion criteria advice can be sought from the local Health Protection team. The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.

Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material, e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Inform/refer to the relevant medical practitioner if individual declines treatment. Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

Name form and strength of vaccine	Combined hepatitis A and typhoid vaccine ViATIM®. ViATIM® is available as a suspension and solution for injection in a pre-filled dual chamber syringe. The dual chamber contains 0.5mL Vi polysaccharide of *Salmonella typhi* (Ty2 strain) and 0.5mL inactivated hepatitis A virus, GBM strain. After reconstitution, 1 dose (1mL) contains 160 units inactivated hepatitis A and 25 micrograms Vi polysaccharide typhoid vaccine.
Legal status	ViATIM® is a Prescription-only Medicine (POM).
Dosage/Maximum total dose	A single dose of 1mL.
Frequency of dose/Duration of treatment	Primary immunisation – one dose should be given at least two weeks prior to risk of exposure to typhoid and hepatitis A. **Monovalent vaccines for hep A and typhoid should be used as boosters.** ViATIM® may be used as a booster vaccine in individuals who have received a primary dose of inactivated hepatitis A vaccine preferably 6 to 12 months previously and also require protection against typhoid fever. The combined vaccine can be given up to 36 months after the monovalent component hepatitis vaccine if necessary. In order to provide long term protection against infection caused by hepatitis A virus, a booster dose of an inactivated monovalent component hepatitis A vaccine should be given preferably 6 to 12 months (but may be given up to 36 months) after a single dose of combined vaccine (reinforcing

	immunisation will give substantial increase in antibody titre and will give immunity beyond 10 years). Those who remain at risk of typhoid should be re-vaccinated with monovalent vaccine every 3 years. A further monovalent booster should be given at 25 years for those at continued risk of hepatitis A.
Maximum or minimum treatment period	N/A
Route/Method of administration	ViATIM® should be administered by slow intramuscular injection in the deltoid region. The vaccine should not be administered in the gluteal region (vaccine efficacy is reduced). Individuals with known bleeding disorders should receive the vaccine by deep subcutaneous route to reduce the risk of bleeding. This vaccine **should not be given** by the intravenous or intradermal routes under any circumstances. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to ViATIM®. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records. The two vaccine components should only be mixed immediately prior to injection. Shake before mixing and again prior to injection to obtain a homogeneous suspension. The contents of the two chambers are mixed by slowly advancing the plunger. The final volume to be injected is 1mL. The vaccine should be visually inspected before administration for any foreign particulate matter. The mixed vaccine is a cloudy, whitish suspension. The vaccine should not be used in case of unexpected particles in it.
Quantity to be administered	A single dose of 1mL.

Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Store in original packaging in order to protect from light. Individual NHS Board guidance on the storage, handling, and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.
Follow-up (if applicable)	Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice. Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied.
Advice (Verbal)	Advise individual what to expect and what to do for minor and major reactions. Advice should be given to use paracetamol or ibuprofen symptomatically for relief of mild pyrexia and aches. Combined hepatitis A and typhoid vaccine is not 100% effective and the importance of scrupulous attention to personal, food and water hygiene, in order to prevent infection, must still be emphasised to those travelling to endemic areas. If access to hand washing facilities is poor advise to carry hand sanitising gel or antibacterial hand wipes. Combined hepatitis A and typhoid vaccine gives no protection against infection by other known liver pathogens including hepatitis B, hepatitis C and hepatitis E viruses. Combined hepatitis A and typhoid vaccine protects only against hepatitis A infection and typhoid fever which is caused by *Salmonella enterica* serotype *Typhi*. Protection is not conferred against paratyphoid fever or infections with any other serotypes of *Salmonella enterica*. Due to the incubation period of hepatitis A disease, infection may be present but not clinically apparent at the time of vaccination. It is not known if combined hepatitis A and typhoid vaccine will prevent symptomatic hepatitis A infection in this case.

	If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24. When administration is postponed advise the individual when to return for vaccination.
Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	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. The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site. Individual may also experience stiffness of the muscle injected for a few days following vaccination. Other common side effects include headache, arthralgia, myalgia, nausea, diarrhoea, malaise and fever. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. **This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.** **BNF**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

	Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically.

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	Registered Nurses as recognised by the Nursing and Midwifery Council (NMC), and Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken PGD training as required/set out by each individual Health Board • Have attended basic life support training either face to face or online and updated in-line with individual Board requirements • Have undertaken immunisation training where available • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and

	management of anaphylaxis updated in-line with individual Board requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct • Have knowledge and familiarity of the following; o Current edition of the Green Book o SmPC for the vaccine to be administered in accordance with this PGD o Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board o Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Nurses working within NHS Shetland can be authorised to administer the drug specified in this PGD by their Nurse Manager/practice GPs. Pharmacists working within NHS Grampian, Highland, Orkney, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of vaccine administration • Individuals name and CHI • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate. • Individual's GP records if appropriate • Individual service specific systems.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk ViATIM®– Date of revision of text 18/02/21, accessed 10/08/21. British National Formulary accessed 10/08/21. BNF British National Formulary - NICE Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book TRAVAX http://www.travax.nhs.uk/ accessed 10/08/21.

	American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

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I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction For The Administration Of Combined Hepatitis A and Typhoid Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**