Patient Group Direction For The Administration Of Combined Hepatitis A and Typhoid Vaccine By Nurses And Pharmacists Working Within NHS Grampian

Lead Author: Medicines Management Specialist Nurse
Consultation Group: See relevant page in the PGD
Approver: Medicine Guidelines and Policies Group

Signature:

Identifier: NHSG/PGD/hepA_typhoid/MGPG797
Review Date: June 2018
Date Approved: June 2016

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the Employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.

Uncontrolled when printed

Version 6
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2016</td>
<td>January 2014</td>
<td>2 yearly update to new PGD template.</td>
<td></td>
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<tr>
<td>April 2016</td>
<td>January 2014</td>
<td>Further information on follow-up booster.</td>
<td>Duration of Treatment.</td>
</tr>
<tr>
<td>April 2016</td>
<td>January 2014</td>
<td>Additional information not thought pertinent to the PGD removed.</td>
<td>Definition of situation/condition.</td>
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</table>

Subject: Patient Group Direction
Identifier: NHSG/PGD/hepA_typhoid/MGPG797
Replaces: NHSG/PGD/hepA_typhoid/MGPG620, Version 5
Keyword(s): PGD Patient Group Direction, hepatitis A, typhoid, combined vaccine, nurses, pharmacists

Policy Statement:

It is the responsibility of individual nurses, pharmacists 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 patient, 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 as well as its dissemination. Pharmacy and Medicines Directorate is responsible for ensuring registration of this document.

Review date: At least every 2 years or sooner if current treatment recommendations change.

Document: Drafted: December 2004
Completed: May 2005
Patient Group Direction for the Administration of Combined Hepatitis A and Typhoid Vaccine by Nurses and Pharmacists Working Within NHS Grampian

Clinical indication to which this PGD applies

**Definition of situation/condition**

This Patient Group Direction (PGD) will authorise nurses and pharmacists to administer hepatitis A and typhoid vaccine for immunisation against typhoid fever and hepatitis A virus infection in adults and children over 15 years of age.

This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), The Green Book and individual Summary of Product Characteristics (SPC).

**Inclusion criteria**

Those aged 15 years or older requiring (Hepatyrix®), or 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.
- NHSG estates staff following risk assessment.
- In the population as defined by the Health Protection Team.

**Exclusion criteria**

- Patients under the age of 15 years (Hepatyrix®) or 16 years (ViATIM®).
- Have known anaphylactic hypersensitivity to any of the excipients. N.B. vaccines may contain neomycin.
- Have a confirmed anaphylactic reaction to a previous dose of the vaccine.
- Patients suffering from acute severe febrile illness (Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered).
- They have a history of severe (i.e. anaphylactic) allergy to latex. Vaccination should be deferred until it can be ascertained that the vaccine to be used is latex-free. Check against SPC or with Medicines Information at ARI (telephone: 01224 552316). For latex allergies other than anaphylactic allergies (e.g. contact allergy to latex) vaccination may proceed as normal.

<table>
<thead>
<tr>
<th>Precautions and special warnings</th>
</tr>
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<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>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 patients may therefore require administration of additional doses. If possible, vaccination should be delayed until the completion of any immunosuppressive treatment.</td>
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<tr>
<td>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.</td>
</tr>
<tr>
<td>Pregnancy and lactation - limited data are available on the safety of combined hepatitis A and typhoid vaccine in pregnancy or during lactation. Refer to a doctor.</td>
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<thead>
<tr>
<th>Referral criteria</th>
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<tbody>
<tr>
<td>Patients who fall into the categories detailed in the exclusion criteria.</td>
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<thead>
<tr>
<th>Action if excluded from treatment</th>
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<tbody>
<tr>
<td>If a patient is excluded from treatment under this PGD, medical advice should be sought – refer to a doctor.</td>
</tr>
<tr>
<td>The reason why the patient was excluded under the PGD will be documented in the patient’s medical notes.</td>
</tr>
</tbody>
</table>
| **Action if patient declines treatment** | Patient should be advised of the risks and consequences of not receiving treatment.  
Give information about when the vaccine may/may not be given, or give a further appointment to attend for vaccination, or in the case of a previous severe allergic reaction refer to the appropriate medical practitioner.  
Give advice about hygiene and avoiding hepatitis A and typhoid infection.  
Record outcome in Patient Medication Record if appropriate and refer the patient to their general practitioner. |
|---|---|
| **Consent** | Prior to the administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG “Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions”. See link below.  

**Description of treatment available under the PGD**

| **Name of medicine** | Combined hepatitis A and typhoid vaccine.  
Hepatyrix® and ViATIM®. |
| **Legal status** | Combined hepatitis A and typhoid vaccines are a Prescription-only Medicine (PoM). |
| **Form/Strength** | Hepatyrix® is presented as a 1mL pre-filled syringe containing inactivated hepatitis A virus (HM175 strain) 1440 ELISA Units and Vi polysaccharide of *Salmonella typhi* (Ty2 strain) 25 micrograms. The normal appearance of the vaccine is a slightly opaque white suspension, which may sediment during storage. |
ViATIM® is available as a suspension and solution for injection in a pre-filled dual chamber syringe. The dual chamber contains 0.5mL purified Vi polysaccharide of *Salmonella typhi* (Ty2 strain) and 0.5mL inactivated hepatitis A strain. After reconstitution, 1 dose (1mL) contains 160 units inactivated hepatitis A and 25 micrograms Vi polysaccharide typhoid vaccine. The hepatitis A component is a cloudy white suspension and the typhoid component is a clear and colourless solution. The two vaccine components should only be mixed immediately prior to injection. Shake before mixing and again before injection to obtain a homogeneous suspension. The mixed vaccine is a cloudy, whitish suspension.

### 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).

The subcutaneous route may be used for patients with thrombocytopenia or bleeding disorders since bleeding may occur following an intramuscular administration to these patients. Firm pressure should be applied to the injection site (without rubbing) for at least two minutes after the injection.

N.B. when concomitant administration with other vaccine(s) is necessary the vaccines must be given at different injection sites, preferably into different limbs. If given in the same limb the injection sites should be at least 2.5cm apart.

### Dosage/Total Dose

A single dose of 1mL.

### Duration of treatment

Primary immunisation – one dose.

In order to provide long term protection against infection caused by hepatitis A virus, a booster dose of an inactivated single 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).

The vaccine should be given at least two weeks prior to risk of exposure to typhoid and hepatitis A.
A further monovalent booster should be given at 25 years for those at continued risk of hepatitis A.

Those who remain at risk of typhoid should be re-vaccinated with monovalent vaccine every 3 years.

**Monovalent vaccines for hep A and typhoid should be used as boosters.**

Hepatyrix®, or ViATIM®, may be used as a booster vaccine in patients 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 single component hepatitis vaccine if necessary.

### Storage requirements

- Store between +2°C and +8°C.
- Do not freeze. If frozen the vaccine should be discarded.
- Protect from light.
- The vaccine should be well shaken before injection and must be visually inspected for foreign particles or variation of physical aspect before use. In the event of either, the vaccine should be discarded.

### Follow-up (if applicable)

- Vaccine recipients should remain under observation until they have been seen to recover from the procedure. It is not possible to specify an exact length of time, but patients should remain on the premises for at least 10 - 15 minutes. Patients should not leave if they are feeling at all unwell without speaking to the nurse/pharmacist first. If necessary a doctor or the patient’s GP should be contacted for advice.
- Advice should be given to use paracetamol or ibuprofen symptomatically for relief of mild pyrexia and aches.
- If more serious adverse or persistent effects occur, the patient/parent/guardian/ person with parental responsibility should be advised to contact their GP/Accident and Emergency Department/NHS 24.
- Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied.
### Advice to patient (Verbal)

Advice should be given on what to expect and what to do for major and minor reactions.

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.

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.

### Advice to patient (Written)

The patient information leaflet contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.

Copies of Patient Information Leaflets and SPCs for all medicines can be found at [http://www.medicines.org.uk](http://www.medicines.org.uk)

### Concurrent Medications/Drug Interactions

There are no special considerations for individuals known to be taking other medicines. If given concomitantly with another vaccine, administration should be at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart.

### Adverse effects and managing possible adverse reactions

The most common adverse effects are pain, swelling and erythema at the injection site. Systemic reactions including headache, fever, malaise, nausea, diarrhoea, dizziness and itch are reported less frequently.

Patients may also experience stiffness of the muscle injected for a few days following vaccination.
Very rarely anaphylactic reactions have been reported. If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

This list is not exhaustive. Please also refer to current BNF and manufacturers SPC for details of all potential adverse reactions.

BNF - https://www.medicinescomplete.com/mc/bnf/current/

SPCs/PILs -
https://www.medicines.org.uk/emc/
http://www.mhra.gov.uk/spc-pil/index.htm

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report the reaction to the MHRA using the Yellow Card System.  https://yellowcard.mhra.gov.uk/

Medical advice in cases of anaphylaxis

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. Medical advice must be sought as soon as possible from a doctor if any patient develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the patient is deteriorating then an emergency ambulance must be called on 999 or direct via ambulance control or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. (Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals).

Facilities and supplies required

The following should be available at sites where the medication is to be supplied / administered:

- Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit).
- An acceptable level of privacy to respect patient’s right to confidentiality and safety.
- Resuscitation equipment.
- 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.
- Copies of the current PGD for the medicine specified in the PGD.
- PGD for the administration of Adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals.

### Characteristics of staff authorised to supply/administer medicine under PGD

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Registered nurses as recognised by the NMC and Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).</th>
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<tbody>
<tr>
<td>Specialist competencies</td>
<td>Be competent to assess the patient’s capacity to understand the nature and purpose of the administration in order for the patient to give or refuse consent.</td>
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<tr>
<td></td>
<td>Has undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD.</td>
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<td></td>
<td>The practitioner must be familiar with the SPC for all medicines supplied in accordance with this PGD.</td>
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<td></td>
<td>Be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient.</td>
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<td></td>
<td>Is competent in the administration of the drug.</td>
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<tr>
<td>Ongoing training and competency</td>
<td>Have attended basic life support training which is required to be updated annually.</td>
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<td></td>
<td>Have undertaken the NHS e-anaphylaxis training session (and annual updates) which covers all aspects of the identification and management of anaphylaxis. This can be accessed via eKSF, or the AT Learning® tool.</td>
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<tr>
<td></td>
<td>Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.</td>
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<tr>
<td>Professional managers/Lead Nurses will be responsible for:</td>
<td>Ensuring that the current PGD is available to staff providing care under this direction.</td>
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<td></td>
<td>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</td>
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</table>
### Documentation

<table>
<thead>
<tr>
<th>Authorisation of administration</th>
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<tbody>
<tr>
<td>Nurses working within NHS Grampian can be authorised to administer the drug specified in this PGD by their Nurse Manager/Consultant/practice GPs. Pharmacists working within NHS Grampian can be authorised to administer the drug specified in this PGD by the Director of Pharmacy. All authorised staff are required to read the PGD and sign the Agreement to administer Medicines under PGD (<a href="#">Appendix 1</a>). A certificate of authorisation (<a href="#">Appendix 2</a>) signed by the authorising doctor/manager should be supplied. This should be held in the individual practitioners records, or as agreed locally.</td>
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<tr>
<th>Record of administration/supply</th>
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| An electronic or paper record for recording the screening of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include:  
- Name and address of patient  
- Patient CHI No and date of birth  
- Details of parent/guardian, or person with parental responsibility where applicable  
- Consultant/General Practitioner details  
- Risk group, if appropriate  
- Findings of physical examination, if appropriate  
- Exclusion criteria, record why drug not administered  
- Reason for giving  
- Consent to the administration (if not obtained elsewhere)  
- Drug manufacturer, batch number and expiry date (Vaccines and injectable medicines)  
- Site where drug administered, dose and route of administration  
- Signature and name in capital letters of practitioner who administered the drug  
- Date drug given  
- Record of any adverse effects (advise patient’s doctor)  
- If vaccines are given information of this administration must be provided to the GP Practice and Practitioner Services Division (PSD) for inclusion on the Scottish Immunisation Recall System (SIRS). |

These records should be retained:  
**For children and young people**, retain until the patient’s 25th birthday or 26th if the young person was 17 at the conclusion of treatment.
**For 17 years and over** retain for 6 years after last date of entry, for 3 years after death, or in accordance with local policy, where this is greater than above.

<table>
<thead>
<tr>
<th>Audit</th>
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<tbody>
<tr>
<td>All records the drug specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each HSCP/practice/service will be responsible for auditing completion of drug forms and collation of data.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>ViATIM® - Date of revision of text 02/03/2015, accessed 07/11/16</td>
</tr>
<tr>
<td>Hepatryix® - Date of revision of text 16/03/15, accessed 07/01/16</td>
</tr>
<tr>
<td>The Pharmaceutical Press</td>
</tr>
<tr>
<td>Travax <a href="http://www.travax.nhs.uk/">http://www.travax.nhs.uk/</a> accessed 07/01/16</td>
</tr>
</tbody>
</table>

**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 of the professional group who will provide care under the direction

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Frances Adamson</td>
<td>Lead Author: Medicines Management Specialist Nurse</td>
</tr>
<tr>
<td>Liz Kemp</td>
<td>Pharmacist: Principal Pharmacist</td>
</tr>
<tr>
<td>Dr Katherine Targett</td>
<td>Medic: Consultant Occupational Physician</td>
</tr>
<tr>
<td>Fiona Browning</td>
<td>Health Protection Nurse Specialist</td>
</tr>
<tr>
<td>Charles Michie</td>
<td>Community Pharmacist</td>
</tr>
<tr>
<td>Morag Hives</td>
<td>Occupational Health Head of Service</td>
</tr>
<tr>
<td>Rhiannon Sharp</td>
<td>Travel Clinic Lead Nurse</td>
</tr>
</tbody>
</table>
Authorising Managers

Dr Nick Fluck
Medical Director, NHS Grampian

Mr David Pfleger
Director of Pharmacy and Medicines Management, NHS Grampian

Ms Amanda Croft
Executive Director of Nursing, Midwifery and AHPs, NHS Grampian
Appendix 1

Health Care Professional Agreement to Administer Medicines Under Patient Group Direction

I: ____________________________ (Insert name)

Working within: ____________________________ e.g. HSCP, Practice

Agree to administer medicines under the direction contained within the following Patient Group Direction

Patient Group Direction For The Administration Of Combined Hepatitis A and Typhoid Vaccine By Nurses And Pharmacists Working Within NHS Grampian

I have completed the appropriate training to my professional standards enabling me to administer medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: ____________________________

Print Name: ____________________________

Date: ____________________________

Professional Registration No: ____________________________
Appendix 2

Certificate Of Authorisation To Administer Medicines Under Patient Group Direction

This authorises: ______________________________________

Working within: ____________________________________ e.g. HSCP, Practice

To administer medicines under the following Patient Group Direction

Patient Group Direction For The Administration Of Combined Hepatitis A and Typhoid Vaccine By Nurses And Pharmacists Working Within NHS Grampian

The above named person has satisfied the training requirements and is authorised to administer medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction

Signed: ___________________________________________ Authorising Manager/Doctor

Print Name: _________________________________________

Date: _____________________________________________