TEESWIDE Patient Group Direction (PGD) for the Administration of
COMBINED HEPATITIS A and TYPHOID VACCINE (HEPATYRIX® and ViATIM®)
by Registered Professionals to Individuals Accessing Services in
NHS Hartlepool, NHS Middlesbrough, NHS Stockton-On-Tees and NHS Redcar & Cleveland

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

**Direction Number:** - TW 2012/004

- **Valid from:** - 1st July, 2012
- **Review date:** - 1st April, 2014
- **Expiry date:** - 30th June, 2014

This patient group direction has been developed & produced by:

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
<td><strong>Senior Pharmacist</strong> (NHS Tees)</td>
<td>Hira Singh</td>
<td></td>
<td>15/6/12</td>
</tr>
<tr>
<td><strong>Public Health Specialist Nurse</strong> (Public Health Tees)</td>
<td>Rachel Fawcett</td>
<td></td>
<td>15/6/12</td>
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<tr>
<td><strong>Clinical Director of Public Health</strong> (Public Health Tees)</td>
<td>Dr. Toks Sangowawa</td>
<td></td>
<td>15/6/12</td>
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This patient group direction has been approved for use in
NHS Hartlepool, NHS Middlesbrough, NHS Redcar & Cleveland and NHS Stockton-On-Tees by:

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<tr>
<td><strong>Senior Medical Adviser</strong> (NHS Tees)</td>
<td>Dr. James Gossow</td>
<td></td>
<td>15/6/12</td>
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PGD for Combined Hepatitis A & Typhoid Vaccine (TW 2012/004). (Review date April 2014/ Expiry 30/06/2014)
1. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/ supervisor/ manager may use this PGD for the indications defined within it.

Under current legislation only the following healthcare professionals with current registration may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include:

<table>
<thead>
<tr>
<th>Pharmacists</th>
<th>Nurses</th>
<th>Chiropodists/Podiatrists</th>
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</thead>
<tbody>
<tr>
<td>Health Visitors</td>
<td>Physiotherapists</td>
<td>Midwives</td>
</tr>
<tr>
<td>Dieticians</td>
<td>Optometrists</td>
<td>Registered Orthoptists</td>
</tr>
<tr>
<td>Prosthetists and Orthotists</td>
<td>Radiographers</td>
<td>Occupational Therapists</td>
</tr>
<tr>
<td>Speech and Language Therapists</td>
<td>Dental Hygienists</td>
<td>Dental Therapists</td>
</tr>
</tbody>
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State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.

Qualifications required (professional registration applies to specific professions)

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council (HPC)

Additional requirements (applies to all staff)

- Maintains knowledge of vaccinations, either through a recognised course or in-house training supported by attendance at vaccination study day(s).
- Up to date resuscitation skills & anaphylaxis training (& competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current, locally authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and Immunisation against infectious disease (Green Book).
- Any additional training requirements as deemed necessary by your organisation.

Continued training requirements (applies to all staff)

- Annual attendance at an accredited update on resuscitation skills and the management of anaphylaxis within the community/primary care (mandatory).
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation (recommended).
- Any additional continued training requirements as deemed necessary by your organisation.
2. Clinical Condition or Situation to Which the Direction Applies

**Indication** (defines situation or condition)
- Patients attending a clinic requesting foreign travel health advice and vaccinations.
- Patients requiring occupational protection;
- Patients at risk of Hepatitis A and Typhoid

**Objectives of care**
To prevent infectious disease; Promote health amongst travellers to foreign countries & to those at occupational risk.

**Inclusion criteria**
- Travellers to areas where there may be exposure to risk of infection from Hepatitis A + Typhoid;
- Those requesting the vaccine for occupational risk.

**Exclusion criteria**

**Specific:**
- Hepatix (GSK): - Children under 15 years of age.
- ViATIM (Sanofi Pasteur MSD): - Children under 16 years of age.

**General exclusions:**
- Have an acute febrile illness or acute severe systemic illness or other active or suspected infection.
- Pregnancy (known or suspected) and during lactation;
- No valid consent.
- Severe general reaction to previously administered dose of combined Hepatitis A + Typhoid vaccine or the monovalent Hepatitis A or Typhoid vaccines;
- Hypersensitivity to any component of the combined or monovalent vaccine(s);
- Hypersensitivity to neomycin;

Refer to current SPC &/or BNF for full list of details.

**Action if excluded** - Discuss with or refer to doctor. Ensure all actions/decisions are documented.

**Action if patient declines treatment**
- Ensure patient, parent or guardian fully understands the risks of declining vaccination & action to be taken if exposed. Advise about protective effects of vaccine & the risks of infection and disease complications.
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate.
### Name, strength & formulation of drug:

Inactivated Hepatitis A + Typhoid Vaccine available as:
- **Hepatyrix** (GSK): (1ml pre-filled syringe); Legal status: POM
- **VIATIM** (Sanofi Pasteur MSD): 1ml (0.5ml + 0.5ml) pre-filled dual chambered syringe Legal status: POM

### Dosage/Dose range:

<table>
<thead>
<tr>
<th>Hepatyrix:</th>
<th>15 years &amp; over:</th>
<th>(25mcg) 1ml</th>
<th>VIATIM:</th>
<th>16 years &amp; over:</th>
<th>(25mcg) 1ml</th>
</tr>
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The vaccine should preferably be given at least two weeks prior to risk of exposure to typhoid & hepatitis A. However, for travel purposes the vaccine can be given up to the day of departure. 
Please note. Antibody levels may not be reached until 14 days after administration of the vaccine.

### Route/Method:

Intra-muscular (IM) injection preferably into the deltoid region.

- **Not** to be given intravenously.
- **Not** to be administered in the gluteal muscle or intradermally since this may result in lower immune response.
- Exceptionally, can be administered subcutaneously in patients with thrombocytopenia or bleeding disorders.

(Please refer to the manufacturer’s SPCs and local PCT immunisation policies/procedures).

### Frequency or Administration:

Subjects who remain at risk of typhoid fever should be revaccinated using a single dose of Vi polysaccharide vaccine every 3 years, unless it is also appropriate to administer a booster of hepatitis A vaccine, in which case Hepatyrix or VIATIM may be used.

<table>
<thead>
<tr>
<th>Hepatyrix</th>
<th>VIATIM</th>
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<tbody>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>15 years and over</td>
<td>16 years and over</td>
</tr>
<tr>
<td>Primary Vaccination</td>
<td>Single dose of 1.0ml</td>
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<tr>
<td>As Booster Vaccinations</td>
<td>Single dose of 1.0ml</td>
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For booster vaccination of Typhoid or Hepatitis A then single component vaccines should be used (Polysaccharide Typhoid Vaccine or Hepatitis A Vaccine as appropriate), *(See relevant PGDs)*.

**Single dose of 1.0 ml**
Preferably between 6 and 12 months following primary immunisation with an inactivated hepatitis A vaccine to subjects who also require protection against typhoid fever. Where a combined hepatitis A and typhoid vaccine has been used to initiate immunisation, a dose of single antigen hepatitis A vaccine will be required 6-12 months later in order to provide prolonged protection vs. hepatitis A infection. Booster doses of the typhoid component will be required at three years.

### Max. dose & duration of treatment + frequency of administration: As above
4. Further Aspects of Treatment:

Relevant Warnings & Potential Adverse Effects & Reporting

Potential Adverse Effects/Reactions: -

Very Common reactions include: -
- Mild & transient soreness; swelling, redness and pain at the injection site. Malaise & myalgia for ViATIM.

Common effects include: -
- Headache, nausea, fever. Loss of appetite and itching (Hepatyrix only). Itching not common with ViATIM.

Uncommon and rare include: -
Generalised rashes occasionally reported. Rarely anaphylaxis and allergic reactions.

Reporting Procedure of Adverse Effects
- Report to doctor & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the CSM using the yellow card system. Otherwise only report if adverse reaction is severe.

See manufacturers Summary of Product Characteristics for details of all potential adverse reactions.

Identification and Management of Adverse Reactions
- See anaphylaxis guidelines
- Patient/Parent/Guardian requested to report side effects
- Advice on management: - (Analgesia for pain &/or fever; apply cold compress/ drink plenty of clear fluids).
- Refer to doctor if appropriate

Advice to Patient/Carer (verbal or written)
- For patients who go on to develop flu-like symptoms, general advice includes; bed rest, fluids and symptomatic remedies. Refer to doctor if general health worsens.
- Explain protection level expected from vaccine. Provide a patient information leaflet and discuss as required.
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above).
- Explain out of hours procedure.
- Explain procedure for dealing with anaphylaxis/severe allergic reactions.
- Explain potential warnings, side effects/adverse effects and request to report them if they occur.
- Give date of next vaccine if applicable.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course) if applicable.

Arrangements for Referral to Medical Advice
- Urgent doctor appointment if appropriate
Further Aspects of Treatment continued:

**Records**

The following must be recorded in the patient's notes:

- Patient's name and date of birth;
- Reason vaccination required;
- Date of administration;
- Dose, site and route of injection;
- Brand name, batch number and expiry date of vaccine;
- Whom administered by and signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications;
- That side effects have been discussed;
- Support literature given (where applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.

**Additional Facilities**

- Store in a refrigerator (+2°C to +8°C). Discard if frozen.
- Stock control & storage of vaccines in accordance with local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1 in 1000 injection (as a minimum).
  (Please refer to current PGD for adrenaline).
- Please be aware of Resuscitation Council Guideline changes (Oct.2010).

**Special Considerations / Additional Information**

**Hepatyrix**

- The vaccine's normal appearance is a cloudy white suspension, which may sediment during storage.
- Before administration, the vaccine should be well shaken to distribute the suspension uniformly and obtain a slightly opaque white suspension.
- Hepatyrix protects only against typhoid fever caused by *Salmonella enterica serotype Typhi*. Protection is not conferred against paratyphoid fever or infections with any other serotypes of *S. enterica*.

**ViATIM**

- 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 compartments are mixed by slowly advancing the plunger. The final volume to be injected is 1 milliliter.
- The vaccine should be visually inspected before administration for any foreign particulate matter. The mixed vaccine is a cloudy, whitish suspension.

**References**

- **Department of Health**: Hepatitis A (Chapter 17) + Typhoid (Chapter 33), Immunisation Against Infectious Disease. The "Green Book" (2006) updated 26/03/12.
- **HSC 2000/026** (9th August 2000): Patient Group Directions; Current edition of BNF;
- **Resuscitation Council (UK)**: Resuscitation Guidelines (October 2010).
- GSK, Hepatyrix® - SPC, 25/01/12 (accessed from Electronic Medicines Compendium on 14/06/12).
This form is to be used for the purpose of managing, monitoring and authorising the use of this PGD by named healthcare professionals.

- Please retain this original PGD & form for future photocopying and use.
- This PGD is to be read, agreed to and signed by all registered healthcare professionals it applies to.
- One signed copy should be given to each healthcare professional with the original signed copy being kept on file by the Manager/Clinical Lead with responsibility for maintaining PGDs.
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare professional: ____________________________

is authorised to give

COMBINED HEPATITIS A and TYPHOID VACCINE (HEPATYRIX® and ViATIM®)

......under this PGD

(By signing this document the healthcare professional is stating that they are competent to work under this PGD & accept full clinical responsibility for any decisions made through the use of this PGD).

Signature of Healthcare Professional: _______________________

Date signed: __________________________

State profession: __________________________

This above named healthcare professional has been authorised to use this PGD by: __________________________

Name of Manager/Clinical Lead: __________________________

Signature of Manager/Clinical Lead: __________________________

Date signed: __________________________

PGD Valid from: 1st July, 2012 | Review Date: 1st April, 2014 | Expiry Date: 30th June, 2014