Patient Group Direction (PGD) for the Administration of

Combined HEPATITIS A + TYPHOID VACCINES (Hepatyrix® & ViATIM ®)

by Registered Professionals to Individuals Accessing NHS Services in Cumbria and North East Sub Region (NHS England North)

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

Direction Number: - **NECSAT 2017/005**

Valid from: 1st March 2017

Review date: 1st December 2018

Expiry date: 31st March 2019

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
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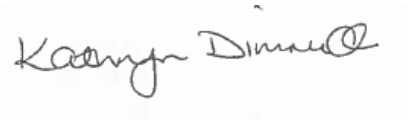
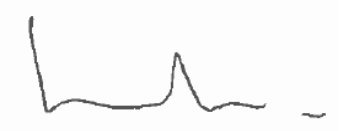
Medicines Optimisation Pharmacist (North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		27/02/17
Assistant Medical Director (NHS England, Cumbria and North East)	**Dr James Gossow** *(Senior Doctor)*		27/02/17
Transforming Care Quality Manager (NHS England, Cumbria and North East)	**Kathryn Dimmick** *(Senior Nurse)*		23/02/17

This PGD has been approved for use in Cumbria and North East Sub Region (NHS England) by:			
Title	Name	Signature	Date
Interim Medical Director (NHS England Cumbria and North East)	**Dr Johnathan Slade** *(Governance Authorisation)*		28/02/17

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

Immunisation against Typhoid and Hepatitis A for individuals aged 15 years or older.

Objectives of care

To prevent infectious disease and promote health. To reduce morbidity & mortality and to eradicate disease.

Inclusion criteria (as per Public Health England (PHE) Green Book Guidance)

Only use those criteria that are specific to your authorised role & competence.
Ensure appropriate consent has been obtained or a best interest decision is in place before commencing any vaccination.

Active immunisation in adults & children aged 15 years old & over, where protection against hepatitis A and typhoid fever is required. These include:

- Travellers to endemic areas with frequent and/or prolonged exposure to conditions where sanitation and food hygiene are likely to be poor.
- Travellers visiting typhoid and hepatitis A-endemic areas whose planned activities put them at higher risk (please check the country information pages www.Nathnac.org and www.travax.nhs.uk)
- Those requesting the vaccine for occupational risk

Exclusion criteria (Refer to current SPC and Green Book Guidance (Online version) for additional details)

General exclusions *(Refer to current Summary of Product Characteristics (SPC) and latest BNF (Appendix 1) for full list of details)***: -**

- No valid consent has been given/ Best Interest decision in place.
- Patient is acutely unwell – (postpone vaccination until recovered. Minor illnesses without fever or systemic upset are not reasons to postpone immunisation).
- Have a confirmed anaphylactic reaction to any ingredient or component of the vaccine. Practitioners must check SPC.
- Any individual who has had an anaphylactic reaction to a previous dose of a typhoid or hepatitis A containing vaccines or any constituents.
- Severe general reaction to previously administered dose of a typhoid or Hepatitis A containing vaccine.
- Severe hypersensitivity to any ingredient or component of the vaccine(s) – **(please also refer to precautions section).**

Specific exclusions:

- **Hepatyrix:** Children under 15 years old
- **ViATIM:** Children under 16 years old

Refer also to current Summary of Product Characteristics (SPC), BNF and Green Book (current on-line version) for full list of details

Precautions

- **Hypersensitivity reactions to previous dose of vaccine or component of vaccine:**
  - **NB**. "Local adverse reactions that generally start within a few hours of the injection and are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens
- Immediate access to epinephrine (adrenaline) 1 in 1000 injection. Syringes and needles of suitable size and capacity for dose should be available.
- **Pregnancy and breast feeding:** - No data are available on the safety of Vi polysaccharide typhoid vaccines in pregnancy or during lactation. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids (Plotkin and Orenstein, 2004). If the risk of typhoid and Hepatits A is high, vaccination should be considered.
- **Individuals with immunosuppression and HIV infection** should still be vaccinated according to the schedule. However they may have a sub-optimal immune response to vaccine. The importance of scrupulous attention to personal, food and water hygiene must be emphasised for immunosuppressed persons travelling to endemic areas. Specialist advice may be required.
- Response to vaccines may be sub-optimal if the patient is immunosuppressed because of disease such as HIV, or treatment e.g. chemotherapy, radiation treatment, steroids or other immunosuppressant drugs.

Action if excluded

- Discuss with or refer to clinician/doctor. Ensure all actions/decisions are documented.
- The risk to the individual of not being immunised must be taken into account.
- If postponement due to acute illness, arrange a future date for immunisation.

Circumstances in which further advice should be sought from doctor and/or specialist

- Patient meeting the exclusion criteria
- Patient requires additional information in order to decide whether or not to have the vaccination
- A Best Interest decision is required for an individual who lacks mental capacity to consent. Seek support from lead clinician responsible for individuals care.

Action if patient declines treatment

- Refusal should be accepted. Ensure patient/guardian/carer fully understands the risks of declining vaccination.
- 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.

2. Description of Treatment.

Name, strength & formulation of drug

Hepatyrix® Injection (GSK) (1ml pre-filled syringe)

- Cloudy white suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber).

ViATIM® Injection (GSK) (1ml (0.5ml+ 0.5ml) pre-filled dual chambered syringe)

- 0.5 ml of suspension in the chamber closest to the plunger and 0.5 ml of solution in the chamber closest to the needle, with a plunger-stopper (Solution and suspension must be mixed before administration of vaccine).

Legal Status:

POM –Prescription Only Medicine.

Dosage/Dose range:

1ml (1 single dose)

Hepatyrix: 15years & over: (Hep A 1440 ELISA Units/ Salmonella typhi 25microgram) **1ml**	**ViATIM:** 16 years & over: (Hep A 160U / Salmonella typhi 25microgram) **1ml**

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:

Intramuscular injection (IM) preferably into the deltoid muscle: -

- For individuals with a bleeding disorder vaccines should be given by deep subcutaneous injection.
- If given at the same time as other vaccines it should be given at separate sites, preferably in a different limb.

(Please refer to the manufacturer's SPCs and on line version of the Green Book for detailed information).

Frequency of Administration:

At least 2 weeks before potential exposure to Typhoid infection.

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

	Hepatyrix	ViATIM
Age	15 years and over	16 years and over
Primary Vaccination	Single dose of 1ml	Single dose of 1ml
As Booster Vaccinations	For booster vaccination of Typhoid or Hepatitis A single component vaccines should be used (Polysaccharide Typhoid Vaccine or Hepatitis A Vaccine as appropriate), **(See relevant PGDs**). **Single dose of 1ml** Preferably between 6 and 12mths 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.	

Please refer to the Immunisation Against Infectious Diseases (Green Book), online Chapters 17 and 33 for full details.

Maximum dose

Maximum dose: **1ml**

Maximum number of vaccinations:

Every 3 years if remaining at risk and both Typhoid and Hepatitis A vaccination is required

Follow up treatment:

If individual remains at risk booster doses are required:

Hepatitis A: 6- 12 months after initial dose. Further booster not required for at least 25years

Typhoid: Every 3 years

Combined vaccine may be administered when both vaccines are required

3. Further Aspects of Treatment:

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See Manufacturers SPC for full details / current Green Book online Chapters 17 and 33

Potential Adverse Effects/ Reactions: - Usually transient and only last a few days after vaccination.

Please be aware of Resuscitation Council Guideline changes (2015)

Very common & Common reactions	• Mild swelling, Erythema, Pain and Redness at injection site. • Fever, Itching, Arthralgia
Less common effects	• Malaise, Myalgia, Headache, Nausea, Diarrhoea and Abdominal pain
Rarely	• Anaphylactic reaction, Syncope, Skin rashes

See Manufacturers SPC for full details of all potential adverse reactions.

Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- **Advice on management including anaphylaxis**: - Chapter 8 of the Green Book provides detailed advice on managing ADRs following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor if appropriate. **Please be aware of Resuscitation Council Guideline changes (2010)**

Please refer to current SPC "special warnings & special precautions for use" section for full details & relevant online chapters of the Green Book.

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All suspected Adverse drug reactions to vaccines occurring in children, or in individuals of any age after vaccines labelled with a black triangle (▼), should be reported to the MHRA using the yellow card scheme.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and Green Book-Chapter 9 See manufacturers Summary of Product Characteristics for details of all potential adverse reactions.

Advice to Patient / Carer (verbal or written)

- Advise patient or carer of need for personal health precautions to reduce risk of typhoid.
- Advice should be given regarding side effects and their management.
- Patients/carers should be reminded that in the event of an adverse reaction they should report it to their GP.
- Explain protection level expected from vaccine. / Provide advice on personal, food and water hygiene.
- 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 and manufacturers SPC).
- Explain procedure for dealing with anaphylaxis /severe allergic reactions. Explain the "Out of Hours" procedure.
- Give date of next vaccine if applicable.
- Complete patient-held vaccination record
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.

Arrangements for Referral to Medical Advice

- Doctor appointment as and when appropriate.
- Additional vaccine related advice may also be obtained from Nathnac (http://www.nathnac.org) and Travax (http://www.travax.nhs.uk) websites.

Records

In all cases manual records including the Personal Held Child Record, computerised records and data collection for Child Health Information Services (CHIS) should include: -

- Patient's name and date of birth;
- Reason vaccination required;
- Date of administration;
- Dose, site and route of injection;
- Brand name, batch number & expiry date of vaccine;
- Whom administered by & signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed; Support literature given (if applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.
- Any immunisation/vaccine related incident should be reported to Cumbria and North East Sub Region (NHS England North).

Additional Facilities

- Access to a current BNF and updated Green Book information
- Store in a refrigerator (+2°C to +8°C). Discard if frozen.
- Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline as applicable)

Special Considerations / Additional Information

- Vaccine can be given at the same time as other vaccines or immunoglobulins, including MMR, HPV, MenC and Hepatitis B vaccine etc, but at a different injection site – either in different limbs or at least 2.5cms from the concomitant immunisation.
- Store vaccines in a clinical refrigerator (+2°C to +8°C)
- The two vaccine components should only be mixed immediately prior to injection.
- 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*.

(Please see updated Green Book – Online version, Chapter 33 and 17 the manufacturer's SPC)

References

- ***NICE****:* Good Practice Guidance (August 2013) – Patient Group Directions.
- ***NHS Executive HSC 2000/026*** (9th August 2000): Patient Group Directions [England only].
- ***NHS England,*** Immunisation Against Infectious Disease– (The Green Book online): Chapter 33 (Typhoid), Accessed at https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book on 21/02/17
- ***NHS England,*** Immunisation Against Infectious Disease– (The Green Book online): Chapter 17 (Hepatitis A), Accessed at https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book on 21/02/17
- ***British National Formulary (BNF)***, current edition. Accessed at http://www.bnf.org/bnf/index.htm on 21/02/17
- ***Nursing and Midwifery Council (NMC), 2007***: Standards for Medicines Management.
- ***Nursing and Midwifery Council (NMC), 2007***: Record Keeping Advice Sheet.
- ***Nursing and Midwifery Council (NMC), 2008***: Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- ***Resuscitation Council (UK),*** Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- Sanofi Pasteur MSD Limited, ViATIM ® - ***Summary of Product Characteristics*** (SPC), updated 17/01/2017 (accessed from Electronic Medicines Compendium on 21/02/2017).
- SmithKline Beecham Limited, Hepatyrix ® - ***Summary of Product Characteristics*** (SPC), update 16/03/2015 (accessed from Electronic Medicines Compendium on 21/02/2017).

Acknowledgement to NHS England North Yorkshire and Humber Area Team for their aid in the development of this PGD

4. 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 currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists
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

Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the HPA National minimum standards in immunisation training 2005 either through training or professional competence ensuring that annual training is offered to all staff
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current 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 or authorising body.

Continued training requirements (applies to all staff)

- Annual attendance at an 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 continued training requirements as deemed necessary by your organisation or the authorising body

Individual Healthcare Professional Authorisation

This form can to be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- 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 administer

Typhoid and Hepatitis A VACCINES (ViATIM ® , Hepatyrix®)

……under this Patient Group Direction (NECSAT 2017/005)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

This above named healthcare professional has been authorised to work under this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from: 1st March 2017	Review Date: - Dec. 2018	**Expiry Date:- 31st March 2019**

Management & Monitoring of Patient Group Direction NECSAT 2017/005

Typhoid and Hepatitis A (ViATIM®, Hepatyrix®) vaccine

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

Typhoid and Hepatitis A (ViATIM®, Hepatyrix®) vaccine under the Patient Group Direction (NECSAT 2017/005)

PGD Valid from date: 1st March 2017 **PGD Expiry Date:** 31st March 2019

Healthcare Professional			**Authorised by:**		
Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

PGD Valid from: 1st March 2017	Review Date: - Dec. 2018	**Expiry Date: - 31st March 2019**