

PATIENT GROUP DIRECTION

**For Administration of
Combined Hepatitis A with Typhoid Vaccine**

Issue Date: 1st September 2011

PGD expiry date: 31st August 2013

Names and signatures of the multidisciplinary group which drew up this PGD

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
Dr Lincoln Sargeant	Consultant in Public Health	Signed on	31.08.2011
Janet Watkinson	Public Health Pharmacist	Signed on	25.08.2011
Penny Miller	Immunisation Coordinator	Signed on	26.08.2011
June Grainger	Practice Nurse	Signed on	26.08.2011
Roisin Wright	Medicines Management Nurse Specialist	Signed on	25.08.2011

Signatures for Ratification

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
Sue Ashwell	Chief Pharmacist	Signed on	30.08.2011
Christine Macleod	Medical Director	Signed on	31.08.2011

Authorisation of Employer (if not employed by NHS Cambridgehire)

NAME	DESIGNATION/TITLE	SIGNATURE	DATE

Each registered practitioner authorised to administer medication under this PGD must have read, understood and signed this version of the PGD and completed the agreement to practice form before attempting to work according to it. Before each administration, it is the responsibility of each practitioner to ensure they are using the most current version and that this document reflects the most up-to-date guidance in 'The Green Book' (DH, 2006)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917.

Staff Characteristics	
All conditions must apply	<p>You must be authorised by name under the current version of this PGD before working to it</p> <ul style="list-style-type: none"> Registered nurse / midwife / health visitor with current registration with the Nursing and Midwifery Council (NMC), employed by NHS Cambridgeshire or an independent contractor within the NHSC Receives training and is competent in all aspects of immunisation including contraindications and the recognition and treatment of anaphylaxis Receives training to undertake administration and supply of medicines under Patient Group Directions Receives updates in immunisation training and travel health according to NHSC requirements Receives updates in CPR and Anaphylaxis in accordance with the NHSC Resuscitation Policy Immediate access to Adrenaline 1:1000 injection A working telephone must be available prior to and during administration of the vaccine Access to “Immunisation against Infectious Diseases 2006” (the Green Book) Maintains own level of updating with evidence of Continued Professional Development (PREP requirements)
Clinical details	
Indication	<ul style="list-style-type: none"> Active immunisation against Hepatitis A virus infection and typhoid fever
Inclusion criteria	<ul style="list-style-type: none"> Valid informed consent Hepatyrix® - adults and adolescents 15 years of age and older ViATIM® - adults and adolescents 16 years of age and older Non-immune adults and adolescents who are at risk of both Hepatitis A and typhoid fever infections from; <ul style="list-style-type: none"> Travel to areas of moderate to high endemicity of both diseases Laboratory staff who work with the organisms or handle specimens from suspected cases
Exclusion criteria	<ul style="list-style-type: none"> No valid consent Hepatyrix®: children under 15 years of age ViATIM®: children under 16 years of age Confirmed anaphylactic reaction to any component of the vaccine including neomycin which may be present in minute amounts Confirmed anaphylactic reaction to a previous dose of either the combined or single component hepatitis A or typhoid vaccines Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered. Patients with HIV– specialist advice is needed, administer using a Patient Specific Direction if appropriate
Action if excluded	<ul style="list-style-type: none"> Refer if appropriate Document findings and action taken in patient’s record Advise when they may have the vaccine if appropriate Give hygiene advice if travelling
Action if patient declines treatment	<ul style="list-style-type: none"> Advise patient of possible consequences of refusing treatment Advise the patient of alternative health care services where they can access the vaccine Advise patient on good personal, water and food hygiene
Handling / use / storage / labelling	<ul style="list-style-type: none"> Vaccines should be stored in the original packaging Refrigerate at +2°C to +8°C. Do not freeze Protect from light The vaccine should be inspected for any foreign particles and/or variation of physical aspect before use. In the event of either being observed, discard the

	<p>vaccine</p> <ul style="list-style-type: none"> • Shake before use
Special precautions	<ul style="list-style-type: none"> • It is possible that patients may be in the incubation period of a hepatitis A infection at the time of vaccination. It is not known whether this vaccine will prevent clinically apparent hepatitis A infections in such cases • This vaccine will not prevent infection caused by other hepatitis- causing agents such as hepatitis B virus, hepatitis C virus, hepatitis E virus or other pathogens known to infect the liver • This vaccine only protects against typhoid fever caused by the <i>Salmonella enterica serotype Typhi</i>. The vaccine does not protect against paratyphoid fever or infections with any other serotype of S enterica • Pregnancy and breastfeeding. There is no evidence of risk from vaccinating pregnant women or those who are breastfeeding with inactivated viral or bacterial vaccines or toxoids. The vaccine should not be withheld from pregnant or breastfeeding women if clinically indicated • Administer vaccine at least 2 weeks prior to risk of exposure to hepatitis A and typhoid. However, if a patient presents for travel advice less than 2 weeks before travel they should still be offered vaccination. The importance of good personal, food and water hygiene must be emphasised to this group of patients as their vaccine response may not be maximal prior to departure. See Advice to Patient section of this PGD • It may be expected that in patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate response may not be achieved. Such patients may therefore require additional doses of vaccine. Seek specialist advice, administer using a Patient Specific Direction if appropriate
Description of Treatment	
Name, form and strength of medicine	<p>Two brands are available</p> <ul style="list-style-type: none"> • Hepatyrix® injection (manufactured by GlaxoSmithKline): one dose (1ml) contains inactivated hepatitis A virus (HM175 strain) 1440 ELISA units combined with Vi polysaccharide of <i>Salmonella typhi</i> (Ty2 strain) 25 micrograms • ViATIM® injection (manufactured by Sanofi Pasteur MSD): 1 dose (1ml) contains inactivated hepatitis A virus (GBM strain) 160 antigen units combined with purified Vi polysaccharide of <i>Salmonella typhi</i> (Ty 2 strain) 25 micrograms
Legal Classification	POM
Black Triangle▼	No
Unlicensed / off label use	No
Dose	<p><u>For adolescents aged 15 years:</u></p> <ul style="list-style-type: none"> • Only Hepatyrix® is licensed to be used • Dose is 1 ml <p><u>For adults and adolescents aged 16 years and older:</u></p> <ul style="list-style-type: none"> • Either Hepatyrix® or ViATIM® can be used • Dose is 1 ml
Route / method	<ul style="list-style-type: none"> • Intramuscular injection (the deltoid region is the preferred site of injection) • The vaccine should not be administered into the gluteal region • The vaccine should not be administered by the intravenous or intradermal routes • 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

	<p>Note: 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</p>
Frequency of administration	<ul style="list-style-type: none"> • 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 • 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 • Patients who remain at risk of typhoid fever should be revaccinated using a single dose of Vi polysaccharide typhoid vaccine every 3 years
Duration of treatment	N/A
Total doses	Single Dose – gives immunity against typhoid for up to 3 years and against Hepatitis A for up to 1 year
Relevant Warnings and adverse drug reactions (ADR)	<ul style="list-style-type: none"> • <u>Very common (≥10%)</u> Pain, myalgia, asthenia, headache, malaise, injection site disorders (pain, induration, oedema, erythema) • <u>Common (≥1% and <10%)</u> General aches, fever, headache, nausea, diarrhoea, itching, arthralgia, swelling • <u>Uncommon (≥0.1% and <1%)</u> Dizziness, pruritis, rash • <u>Very rare (<0.01%)</u> Urticaria, convulsions, allergic reactions including anaphylaxis and anaphylactoid reactions, syncope • <u>In addition</u> Other adverse events that have been reported with the single component hepatitis A or typhoid vaccines include vomiting, loss of appetite, abdominal pain, injection site nodule, transaminases increased (mild and reversible), serum sickness, aggravation of asthma, neurological manifestations including transverse myelitis, Guillain-Barre syndrome, paraesthesia and neuralgic amyotrophy, convulsions <p>Appropriate facilities for the management of anaphylaxis should always be available during vaccination sessions</p> <p>Adverse Drug Reactions must be recorded and the patient's GP informed</p> <p>For established medicines, report all serious suspected reactions in adults, and all serious AND minor reactions in children (under 18 years) via the Yellow Card reporting scheme</p> <p>For medicines showing the black triangle ▼ symbol ALL suspected ADRs should be reported via the Yellow Card reporting scheme</p>
Drug Interactions	<ul style="list-style-type: none"> • The vaccine must not be mixed with other drugs in the same syringe • The effect of concomitant administration of immunoglobulins on the immunogenicity of this vaccine has not been assessed. Interference with the immune response cannot be ruled out. However, the vaccine and human normal immunoglobulin may be given at the same time, but in different sites, when both rapid and prolonged protection is required against hepatitis A

Advice to patient	<ul style="list-style-type: none"> • Administration and side effects to be discussed prior to immunisation • Temperature control and management of local reactions • Information on further contacts and out-of-hours services if later required • Provide Patient Information Leaflet if available • Advise patient on the modes of transmission of hepatitis A and typhoid and on good personal, food and water hygiene • Advise that 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 • Advise that patients who remain at risk of typhoid fever should be revaccinated using a single dose of Vi polysaccharide typhoid vaccine every 3 years
Records and follow up	
Follow-up or referral arrangements	<ul style="list-style-type: none"> • Advise of next vaccination date • Immunocompromised patients may respond less well to the vaccine, post immunisation testing for hepatitis A antibodies should be considered
Details of records to be kept	<ul style="list-style-type: none"> • Record that valid informed consent was given • Name of patient, address, date of birth and GP • Name of member of staff who administered the vaccine • Date of treatment • Dose administered, site and route • Manufacturer of product, brand, batch number and expiry date • Advice given if excluded or declines treatment • If given at a travel clinic record how the patient's central record or GP surgery record will be updated • Details of any ADRs and actions taken <p>All records should be clear, legible and contemporaneous The information should be recorded as appropriate in</p> <ul style="list-style-type: none"> • Patient-held record or Personal Child Health Record (PCHR, the Red Book) for children • Patient's GP record or other patient record, depending on location • GP practice computer system <p>A computer or manual record of all individuals receiving treatment under this PGD should also be kept for audit purposes</p>

Each registered practitioner authorised to administer medication under this PGD must have read, understood and signed this version of the PGD and completed the agreement to practice form before attempting to work to it.

It is the responsibility of each individual practitioner to ensure that before each administration they are using the most up-to-date version of any PGD. They should also ensure that the PGD they are using corresponds to current clinical practice as per the Green Book (DH, 2006) http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917 and advised to notify the Medicines Management Team where electronic links to websites do not work or where the guidance within PGDs required updating.

References

- BNF 61 March 2011, chapter 14.4 available online at <http://bnf.org/bnf/bnf/current/> accessed 31.08.2011
- Department of Health, Immunisation Against Infectious Diseases 2006 “The Green Book” plus update to typhoid chapter 33; and hepatitis A chapter 17; available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917 accessed 15.08.2011
- NMC (2008) The Code. Standards of conduct, performance and ethics for nurses and midwives, available online at <http://www.nmc-uk.org/aArticle.aspx?ArticleID=3056> accessed 31.08.2011
- NMC (2010) Standards for medicines management, available online at <http://www.nmc-uk.org/Documents/Standards/nmcStandardsForMedicinesManagementBooklet.pdf> accessed 31.08.2011
- Summary of Product Characteristics for ViATIM (last updated 04.12.2009), Sanofi Pasteur MSD, available online at <http://www.medicines.org.uk/EMC/medicine/7684/SPC/ViATIM/> accessed 31.08.2011
- Summary of Product Characteristics for Hepatyrix (last updated 16.12.2009), GlaxoSmithKline, available online at <http://www.medicines.org.uk/EMC/medicine/2537/SPC/Hepatyrix/> accessed 31.08.2011

AGREEMENT BY HEALTH PROFESSIONAL TO ACT UNDER THE PATIENT GROUP DIRECTION

I have read and fully understand the following documents:

1. The Patient Group Direction:
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2. Issue date: Expiry date:
3. BNF and SPC monographs (and for Immunisation & Vaccination, the appropriate chapters of the Green Book) for all drugs included in this PGD.
4. The NHS Cambridgeshire Patient Group Direction Policy

I agree to act within the terms of the Patient Group Direction and administer and/or supply medicines in accordance with the documents listed above.

I understand that my employer e.g. GP practice or NHS Cambridgeshire, is vicariously liable for acts and omissions by me during my employment with them.

I understand that failure to comply with the terms and conditions of the PGD, including the expiry date and limitations on practitioners, patients, drugs and indications may render me liable to disciplinary action by my employer e.g. GP practice or NHSC under their performance and conduct arrangements.

BY SIGNING THIS PATIENT GROUP DIRECTION 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 PRACTICE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE

NAME: *(block capitals)* (Health Professional)

SIGNATURE: (Health Professional)

POSITION:

EMPLOYER:

SITE/PRACTICE:

DATE SIGNED:

The original must be filed in the health professional's personal file and a copy held by their manager or employer for the purposes of ensuring practice occurs only in accordance with the PGD and is only undertaken by approved practitioners.