

PATIENT GROUP DIRECTION

**For Administration of
Combined Hepatitis A and Hepatitis B 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 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 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 and Hepatitis B virus infection
Inclusion criteria	<ul style="list-style-type: none"> Valid informed consent required Children aged over 1 year old and adults Non immune children, adolescents and adults who are at risk of both hepatitis A and hepatitis B infections from; <ul style="list-style-type: none"> Travelling to countries where both diseases are endemic Laboratory workers handling contaminated specimens Occupational or lifestyle risk
Exclusion criteria	<ul style="list-style-type: none"> No valid consent Confirmed anaphylactic reaction to any component of the vaccine Confirmed anaphylactic reaction to a previous dose of a hepatitis A or hepatitis B containing vaccine Minor illnesses without fever or systemic upset are not reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered Children aged less than one year of age Patients who require post-exposure prophylaxis following percutaneous (needle-stick), ocular or mucous membrane exposure to hepatitis B 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 Advise when they may have the vaccine Give hygiene advice if travelling Document findings and action taken in patient's record
Action if patient declines treatment	<ul style="list-style-type: none"> Advise patient of the indication for the vaccine Advise patient of alternative healthcare services where they can access the vaccine Advise patient of the modes of transmission of hepatitis A and hepatitis B viruses and how to minimise the risk of contracting either virus Give hygiene advice if travelling Document refusal and advice given in patient's record

Handling / use / storage / labelling	<ul style="list-style-type: none"> • Vaccines should be stored in 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 in physical aspect before use. In the event of either being observed, discard the vaccine • Shake before use
Special precautions	<ul style="list-style-type: none"> • Due to the long incubation period of hepatitis B it is possible for unrecognised hepatitis B to be present at the time of vaccination. The vaccine may not prevent hepatitis B in such cases • The vaccine will not prevent infection caused by other agents such as hepatitis C and E and other pathogens known to infect the liver • When using the Ambirix® brand, protection against hepatitis B infection may not be obtained until after the second dose Therefore - <ul style="list-style-type: none"> ○ Ambirix® should only be used when there is a relatively low risk of hepatitis B infection during the vaccination course ○ It is recommended should be administered in settings where completion of the two-dose course can be assured • If rapid protection against hepatitis A is required for adults, e.g. following exposure or during outbreaks, then a single dose of monovalent vaccine is recommended. If rapid protection against Hepatitis A is required for children under 16 years, a single dose of Ambirix® may be used Both vaccines contain the higher amounts of hepatitis A antigen and will therefore provide hepatitis A protection more rapidly than Twinrix® • The vaccine has not been tested in patients with impaired immunity. In such patients the anticipated immune response may not be achieved after the primary immunisation course therefore such patients may require additional doses of vaccine. Specialist advice must be sought and the vaccine may be administered using a Patient Specific Direction from an appropriate practitioner • 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. Hepatitis B infection in pregnancy may result in severe disease for the mother and chronic infection in the newborn. The vaccine should be given where the woman is at definite risk of infection with both viruses • Patients with HIV and impaired immune response. In such patients the anticipated immune response may not be achieved after the primary immunisation course therefore such patients may require additional doses of vaccine. Specialist advice must be sought and the vaccine may be administered using a Patient Specific Direction from an appropriate practitioner
Description of Treatment	
Name, form and strength of medicine	<p>Two brands are covered by this PGD.</p> <ul style="list-style-type: none"> • Ambirix® injection ▼ (manufactured by GlaxoSmithKline): suspension of inactivated hepatitis A virus 720 ELISA units/mL and recombinant hepatitis B surface antigen 20 micrograms/mL available as 1mL prefilled syringe • Twinrix® injection (manufactured by GlaxoSmithKline): inactivated hepatitis A virus 720 ELISA units and recombinant hepatitis B surface antigen 20 micrograms/mL available as 1mL prefilled syringe (Twinrix® Adult) or a 0.5mL prefilled syringe (Twinrix® Paediatric)
Legal Classification	POM

Black Triangle▼	<p>Yes - for Ambirix® brand No- for Twinrix® brand</p> <p>For medicines showing the black triangle all suspected ADRs should be reported via the Yellow Card reporting scheme</p>
Unlicensed / off label use	No
Dose	<p>This varies with the brand used;</p> <ul style="list-style-type: none"> • Adult and child over 16 years of age one brand is available; <ul style="list-style-type: none"> ○ Twinrix® Adult brand Dose is 1mL (equivalent to inactivated hepatitis A virus 720 ELISA units and hepatitis B surface antigen 20 micrograms) • Children aged 1- 15 years two brands are available; <ul style="list-style-type: none"> ○ Ambirix® brand Dose is 1mL (equivalent to inactivated hepatitis A virus 720 ELISA units and hepatitis B surface antigen 20 micrograms) ○ Twinrix® Paediatric brand Dose is 0.5mL (equivalent to inactivated hepatitis A virus 360 units and hepatitis B surface antigen 10 micrograms) <p>The brands should not be used interchangeably. Primary courses should be completed with the same brand of vaccine. Single component vaccines given at appropriate intervals may be used for booster dose</p>
Route / method	<ul style="list-style-type: none"> • Intramuscular injection. The deltoid muscle is the preferred site of injection in adults and older children. Anterolateral thigh is preferred in younger children. • Deep subcutaneous route should be used for individuals with bleeding disorders • The vaccine should not be administered into the buttock or intradermally since this may result in a lower immune response. • Not to be administered intravenously • May be given concomitantly with other vaccines using separate sites and syringes. 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. The site at which each vaccine was given should be recorded in the individual's records.
Frequency of administration	<p>Primary immunisation schedule</p> <ul style="list-style-type: none"> • Ambirix® 2 doses of 1mL at 0 and 6-12 months. • Twinrix® Adult 3 doses of 1 mL at 0, 1 month and 6 months • Twinrix® Paediatric 3 doses of 0.5mL at 0, 1 month and 6 months <p>Accelerated schedule (suitable for adult and adolescent travellers aged over 16 years departing within 1 month)</p> <ul style="list-style-type: none"> • Twinrix® Adult 4 doses of 1mL given on day 0, day 7, day 21 then the fourth dose 12 months after the first dose
Duration of treatment	N/A
Total doses	<ul style="list-style-type: none"> • Ambirix® - 2 doses • Twinrix® Adult and Twinrix® Paediatric – 3 doses for primary immunisation, 4 doses if using the accelerated schedule of Twinrix®

	Adult
Relevant Warnings and Adverse Drug Reactions (ADR)	<ul style="list-style-type: none"> • Very common ($\geq 1/10$) Headache, pain and redness at injection site, fatigue, appetite lost, irritability/fussiness • Common ($\geq 1/100$ to $< 1/10$) Gastrointestinal symptoms, diarrhoea, nausea, swelling at the injection site, injection site reactions (such as haematoma, pruritus, bruising), malaise, drowsiness, fever • Uncommon ($\geq 1/1000$ to $< 1/100$) Dizziness, vomiting, abdominal pain, myalgia, upper respiratory tract infection, fever ($\geq 37.5^{\circ}\text{C}$), rash • Rare ($\geq 1/10\ 000$ to $< 1/1000$) Lymphadenopathy, hypoaesthesia, paraesthesia, pruritis, arthralgia, decreased appetite, hypotension, influenza like illness, chills, urticaria • Frequency unknown (reported for either combined or monovalent hepatitis A and hepatitis B vaccines) Thrombocytopenia, thrombocytopenic purpura, encephalitis, encephalopathy, neuritis, neuropathy, paralysis, convulsions, angioneurotic oedema, lichen planus, erythema multiforme, erythema exsudativum multiforme, arthritis, muscular weakness, meningitis, vasculitis, anaphylaxis, allergic reactions including anaphylactoid reactions and mimicking serum sickness, abnormal liver function tests, multiple sclerosis, myelitis, facial palsy, polyneuritis such as Guillain-Barre syndrome (with ascending paralysis), optic neuritis, syncope <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"> • None known
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 a patient information leaflet if available • Advise patient/ parent/ guardian on the modes of transmission of hepatitis A and hepatitis B and measures to prevent transmission and exposure
Records and follow up	
Follow-up and / or referral arrangements	<ul style="list-style-type: none"> • Next vaccination date is advised if appropriate • Serology testing for hepatitis B post primary course vaccination if appropriate
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 • Advice given if excluded or declines treatment

- Record how the patient's central record or GP surgery record will be updated
- Details of any ADRs and actions taken

All records should be clear, legible and contemporaneous

The information should be recorded as appropriate in

- 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
- Child Health Information System (CHIS)
- GP practice computer system

A computer or manual record of all individuals receiving treatment under this PGD should also be kept for audit purposes

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

- Department of Health, Immunisation Against Infectious Diseases 2006 "The Green Book" plus update to hepatitis A chapter 17; and hepatitis B chapter 18; available online at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917 accessed 31.08.2011
- BNF 61 March 2011, chapter 14.4 available online at <http://bnf.org/bnf/bnf/current/> accessed 31.08.2011
- 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 Twinrix® Adult Vaccine (GlaxoSmithKline UK) available online at <http://www.medicines.org.uk/EMC/medicine/2061/SPC/Twinrix+Adult+Vaccine/> (last updated 12.07.2011) and accessed 31.08.2011
- Summary of Product Characteristics for Twinrix® Adult Suspension For Injection (GlaxoSmithKline UK) available online at <http://www.medicines.org.uk/EMC/medicine/24767/SPC/Twinrix+Adult%2c+suspension+for+injection/> (last updated 25.07.2011) and accessed 31.08.2011
- Summary of Product Characteristics for Twinrix® Paediatric Vaccine (GlaxoSmithKline UK) available online at <http://www.medicines.org.uk/EMC/medicine/2062/SPC/Twinrix+Paediatric+Vaccine/> (last updated 02.12.2011) and accessed 31.08.2011
- Summary of Product Characteristics for Ambirix® suspension for injection (GlaxoSmithKline UK) available on <http://www.medicines.org.uk/EMC/medicine/20491/SPC/Ambirix+suspension+for+injection/> (last updated 03.06.2011) and 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.