Patient Group Direction (PGD) for the Administration of

COMBINED HEPATITIS A+B VACCINES

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 2017/003**
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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Transforming Care Quality Manager (NHS England, Cumbria and North East)	**Kathryn Dimmick** *(Senior Nurse)*		22/02/17

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 Hepatitis A and Hepatitis B infection in adults and children aged 1 year or over.

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).

Those adults and children from 1 year of age who are at increased risk of infection from Hepatitis A & B and where valid consent has been given/ best Interest decision is in place. These include: -

- Patients who are at risk from infection arising during the receipt of medical care;
- Individuals receiving regular blood or blood products (e.g. Haemophiliacs) & carers responsible for the administration of such products;
- Where rapid protection is required against hepatitis A in children ≤ 15 years old, a single dose of Ambirix may be used.
- Those in residential accommodation with learning difficulties;
- Adults and children in day care, schools and centres for those with severe learning disability based on individual risk assessment;
- Close family contacts of a case or individual with chronic hepatitis B infection;
- Families adopting children from countries with a high/intermediate prevalence of hepatitis B;
- Short-term foster carers (and their families) receiving emergency foster placements;
- Permanent foster carers (& their families) adopting/fostering children known to be at high risk of Hepatitis B;
- Individuals who change sexual partners frequently;
- Men who have sex with men;
- Male and female commercial sex workers;
- Injecting drug users (including those who inject intermittently);
- Sexual partners of injecting users;
- Those likely to "progress" to injecting, (e.g. currently smoking heroin);
- Children of injectors;
- Non-injecting user living with current injector;
- Inmates of custodial institutions;
- Those with chronic liver disease & chronic renal failure (See also the Additional Information section);
- Travellers to areas of high or intermediate prevalence where there may be exposure to risk of infection and who are at increased risk, or who intend to remain for lengthy periods. (See Green Book, chapter 18, page 171 for additional details).

- ***Refer to chapters 17 & 18 of the current "Green Book" for full details of inclusion.***

Additional vaccine related advice may also be obtained from Nathnac (http://nathnac.net/) and Travax (http://www.travax.nhs.uk) websites

Exclusion criteria

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

- No valid consent /Best Interest decision in place.
- Children under 12 months of age.
- 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.
- Have a confirmed anaphylactic reaction to a previous dose of a hepatitis A or hepatitis B containing vaccine.
- Severe hypersensitivity to any ingredient or component of the vaccine(s) – **(please also refer to precautions section).**
- Not recommended for post exposure prophylaxis (e.g. needle stick injury, ocular, or mucous membrane exposure to hepatitis B virus).

Specific exclusions:

- Ambirix **is not** recommended as a booster dose following a two dose primary course (Refer to "Additional Information" section).
- Ambirix or Twinrix Paediatric vaccines: - **Not suitable** for individuals 16 years old and over.
- Twinrix Adult vaccine: - **Not to be used** for children aged 15 years old and under.

Refer to current Summary of Product Characteristics (SPC) / Green Book (current on-line version)/ latest BNF 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 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.

- Persons with impaired immune systems or in haemodialysis patients, as adequate antibody titres may not be achieved.

- **When two or more injections need to be administered at the same time**, they should be given at separate sites, preferably in a different limb. If more than one injection is to be given in the same limb they should be administered at least 2.5cm apart.

- **Pregnancy and breast feeding:**
  Hepatitis A containing vaccines can be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines or toxoids.

- **Individuals with immunosuppression and HIV infection** can be given the vaccination but sero-conversion and antibody titre may be low. Re-immunisation should be considered and specialist advice may be required.

Action if excluded

- There are few individuals who cannot receive hepatitis A containing vaccines. **When there is doubt or reason for caution, discuss with or refer to clinician/doctor/local communicable disease specialist.**
- 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 a 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 vaccination refused

- 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 If postponement due to acute illness, arrange a future date for immunisation
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate

Special Considerations / Additional Information

Twinrix Adult

- Protective levels of anti-HAV antibodies predicted to persist for at least 10 years.
- Subjects primed with Twinrix Adult may be administered as booster dose of either of the monovalent vaccines.
- Before use, the vaccine should be well shaken to obtain a slightly opaque, white suspension.

Twinrix Paediateric

- Subjects primed with Twinrix Paediatric may be administered as a booster dose of either of the monovalent vaccines, e.g. hepatitis A or hepatitis B.
- Before use, the vaccine should be well shaken to obtain a slightly opaque, white suspension.

Ambirix

- Where a booster dose of hepatitis A and/or hepatitis B is desired, a monovalent or combined vaccine can be given (Refer to SPC).
- Before use, the vaccine should be well shaken to obtain a slightly opaque, white suspension.

2. Description of treatment

Name, strength & formulation of drug

Inactivated Hepatitis A + B Combined Vaccine available as: -

Twinrix Adult®	(GSK): -	1ml	pre-filled syringe with rubber butyl stopper (Uniform hazy white suspension after resuspension)
Twinrix Paediatric®	(GSK): -	0.5ml	pre-filled syringe with rubber butyl stopper (Uniform hazy white suspension after resuspension)
Ambirix®	(GSK): -	1ml	pre-filled syringe with rubber butyl stopper (Turbid white suspension)

Legal Status:

POM –Prescription Only Medicines

Dosage /Dose range

Twinrix Adult®:	16 years old and over:	**1ml**	(Hep A 720 ELISA units / Heb B 20microgram)
Twinrix Paediatric®:	1-15 years old:	**0.5ml**	(Hep A 360 ELISA units / Heb B 10microgram)
Ambirix®:	1-15 years old:	**1ml**	(Hep A 720 ELISA units / Heb B 20microgram)

Route/Method

Intramuscular injection (IM) is the preferred route: -

- **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.
- If necessary may be given at the same time as other vaccines, but at a separate site, preferably in a different limb. If given in the same limb, they should be given at least 2.5cm apart.

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

Frequency of Administration

PRIMARY COURSE

	Recommended standard Primary course		Accelerated schedule (≥16yrs old only)
Vaccine	**Twinrix Adult** **Twinrix Paediatric**	**Ambrix**	**Twinrix Adult** Only to be used in exceptional circumstances in adults (≥16yrs old), when travel is anticipated within 1 month or more after initiating the vaccination course, but where insufficient time is available to allow the standard 0, 1 and 6 month schedule to be completed, a schedule of 3 injections given at 0, 7 and 21 days may be used. When this schedule is applied a 4th dose is recommended 12mths after 1st dose
Dosage	Consists of **3 doses**	Consists of **2 doses**	Consists of **4 doses**
1st dose	At the elected date	At the elected date *	At the elected date
2nd dose	1 month after the 1st dose	6 to 12 months after the 1st dose	7 days after 1st dose
3rd dose	6 months after the 1st dose		21 days after 1st dose
4th dose			Booster dose recommended 12 months after 1st dose

- **Once initiated the primary course of vaccination should be completed with the same vaccine.**
- * The first dose of Ambirix provides equivalent protection to a primary course of single hepatitis A vaccine, although protection against hepatitis B is not complete until after the second dose.

- Protection from a primary course lasts for at least one year.
- **Where rapid protection against hepatitis A in adults** is required, e.g. following exposure or during outbreaks, then a single dose of monovalent vaccine is preferred, (See Hepatitis A PGD NECSAT 2017/001).
- **For rapid protection against hepatitis A in under 16 year olds**, a single dose of Ambirix may also be used.
- Where a booster dose of both hepatitis A & hepatitis B are desired, Twinrix Adult & Twinrix Paediatric can be used. Alternatively, subjects primed with these may be administered a booster dose of either of the monovalent vaccines.
- **For post-exposure prophylaxis against hepatitis B:** Use an accelerated schedule of monovalent hepatitis B vaccine (or a combined vaccine of equivalent strength) should be used and **given at zero, one** and **two** months. (Please refer to **"Follow up Treatment"** section below.

Maximum dose & number of treatments

Maximum single dose: -

Twinrix Adult and Ambirix: **1ml** (Hep A 720 ELISA units / Heb B 20microgram)

Twinrix Paediatric: **0.5ml** (Hep A 360 ELISA units / Heb B 10microgram)

No. of treatments: - dependant on product and schedule. See above & follow up treatment.

- Completion of primary course will provide protection against *Hepatitis A* for at least 10yrs.

Follow up treatment

Follow current on-line Green Book recommendations as applicable:

Further booster doses for patients who remain at continued risk: -

Single component vaccines should be used.

- Single booster with monovalent Hepatitis A vaccine 25 years after primary course, (i.e. at 25 yearly intervals).
- Single booster dose of Hepatitis B only once, around 5 years after primary course.
- Booster dose(s) of Hepatitis B after exposure to hepatitis virus.

Post exposure prophylaxis: -

- An accelerated schedule of monovalent hepatitis B vaccine (or a combined vaccine of equivalent strength) should be used, with vaccine given at **zero, one and two months**.
- For those at continued risk of exposure to Hepatitis B virus, a 4th (booster) dose at 12 months is recommended. If HBIG is also indicated it should be given as soon as possible, ideally at the same time as the 1st dose.

Additional information: -

- A single dose of monovalent hepatitis A vaccine will provide more rapid protection than the combined preparations where more than one dose is required.
- In situations where a booster dose of hepatitis A and/or hepatitis B is desired a monovalent or combined vaccine can be given.
- 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.

3. Further Aspects of Treatment

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See manufacturers SPC for full details / current Green Book online Chapter 17 & 18

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

Please be aware of Resuscitation Council Guidelines

Very Common & Common reactions Include:	• Injection site reactions such as: mild & transient soreness; swelling, redness and pain at the injection site. (Local reactions within 48hrs after vaccination and persisting for 1-2 days). • Headache, fatigue, nausea, malaise, decreased appetite (rare with Twinrix Adult). • Drowsiness, fever, irritability (Ambirix & Twinrix Paed); Diarrhoea (uncommon in Twinrix Paed).
Less common effects include: -	• Myalgia, vomiting and upper respiratory tract infection. • Fever (≥37.5C) (Twinrix Adult only); Dizziness (Ambirix and Twinrix Adult); • Rash and diarrhoea (Twinrix Paediatric);
Rare and very rare	• Anaphylactic and allergic reactions • Influenza like chills (Ambirix & Twinrix Paed); Rash and pruritus (Ambirix & Twinrix Adult)

This list is not exhaustive. Please also refer to current manufacturers SPC for details of all potential adverse reactions and on line version of the Green Book for detailed information.

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 adverse drug reactions (ADRs) following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor/specialist as appropriate

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and the online Green Book - Chapter 9.

  See manufacturers SPC for details of all potential adverse reactions.

Advice to Patient / Carer (verbal or written)

- 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 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.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.
- Complete patient-held vaccination record (where applicable)

Arrangements for Referral to Medical Advice

- Doctor/specialist 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, computerised records and data collection should include: -

- Patient's name and date of birth;
- Reason vaccination required;
- Date of administration;
- Confirmation that consent has been obtained;
- 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 (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 & Nth East Sub region (NHS England North).

Additional Facilities

- Access to updated online Green Book information; the latest SPC and BNF.
- Store in a clinical refrigerator (+2°C to +8°C). 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)

References

- NICE Good Practice Guidance 02 : Patient Group Directions Aug 2013
- Public Health England*:* Immunisation Against Infectious Disease - The "Green Book" Chapter 17: Hepatitis A Accessed at https://www.gov.uk/government/publications/hepatitis-a-the-green-book-chapter-17 on 16/02/2017
- Public Health England*:* Immunisation Against Infectious Disease - The "Green Book" Chapter 18: Hepatitis 18 Accessed at https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18 on 16/02/2017
- British National Formulary (BNF), Accessed at http://www.bnf.org/bnf/index.htm on 21/02/2017
- Nursing and Midwifery Council (NMC), 2007: Standards for Medicines Management.
- Nursing and Midwifery Council (NMC), 2007: Record Keeping Advice Sheet.
- NMC, 2008: Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- Resuscitation Council (UK), October 2015: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- GlaxoSmithKline Ltd; Ambirix® vaccine – SPC, 23/11/16 (accessed from Electronic Medicines Compendium on 21.2.17). http://www.medicines.org.uk/emc/medicine/20491
- GlaxoSmithKline Ltd; Twinirix Adult® vaccine – SPC, 24/11/16 (accessed from Electronic Medicines Compendium on 21.2.17). http://www.medicines.org.uk/emc/medicine/2061
- GlaxoSmithKline Ltd; Twinrix Paediatric® vaccine – SPC, 24/11/16 (accessed from Electronic Medicines Compendium on 21.2.17). http://www.medicines.org.uk/emc/medicine/2062

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 online version).
- 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.

Management & Monitoring of Patient Group Direction NECSAT 2017/003

The Administration of

COMBINED HEPATITIS A+B VACCINES
(Ambirix®, Twinrix Adult® and Twinrix Paediatric®)

Individual Healthcare Professional Authorisation

This form can 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:-_____

I have read and understood the Patient Group Direction.

COMBINED HEPATITIS A+B VACCINES

I agree to administer Combined Hepatitis A+B Vaccine only in accordance with this Patient Group Direction (NECSAT 2017/003)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

I agree that the above named healthcare professional is authorised to administer medicines in accordance with 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 2017/003

The Administration of

COMBINED HEPATITIS A+B 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

Combined Hepatitis A+B Vaccine under the Patient Group Direction (NECSAT 2017/003)

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**