

**PATIENT GROUP DIRECTION**

**For Administration of  
Meningococcal Group C Conjugate Vaccine to Children and Adults**

**Issue Date:** 1<sup>st</sup> September 2011

**PGD expiry date:** 31<sup>st</sup> 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
Dr Christine Macleod	Medical Director	Signed on	31.08.2011

**Authorisation of Employer (if not employed by NHS Cambridgeshire)**

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](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917).

<b>Staff Characteristics</b>	
<b>All conditions must apply</b>	<p><b>You must be authorised by name under the current version of this PGD before working to it</b></p> <ul style="list-style-type: none"> <li>• 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</li> <li>• Receives training and is competent in all aspects of immunisation including contraindications and the recognition and treatment of anaphylaxis</li> <li>• Receives training to undertake administration and supply of medicines under Patient Group Directions</li> <li>• Receives updates in immunisation training and travel health according to NHSC requirements</li> <li>• Receives updates in CPR and Anaphylaxis in accordance with the NHSC Resuscitation Policy</li> <li>• Immediate access to Adrenaline 1:1000 injection</li> <li>• A working telephone must be available prior to administration of the vaccine</li> <li>• Access to “Immunisation against Infectious Diseases 2006” (the Green Book)</li> <li>• Maintains own level of updating with evidence of Continued Professional Development (PREP requirements)</li> </ul>
<b>Clinical details</b>	
<b>Indication</b>	<ul style="list-style-type: none"> <li>• Immunisation against the invasive disease caused by Neisseria Meningitidis Serogroup C</li> </ul>
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Valid informed consent required</li> <li>• All children over two months of age – Previously assessed by a doctor (usually at six week development check) and considered fit to receive the immunisation programme</li> <li>• Unimmunised people up to 25 years of age</li> <li>• Patients with cochlear implants</li> <li>• Immediate family and close contact of cases of meningococcal infection with Group C organisms and during local outbreaks, in addition to chemoprophylaxis</li> </ul> <p>For further details refer to the BNF, Green Book and SPC</p>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• No valid consent</li> </ul> <p>The vaccine should not be given to those who have had:</p> <ul style="list-style-type: none"> <li>• A confirmed anaphylactic reaction to a previous dose of the vaccine</li> <li>• A confirmed anaphylactic or hypersensitivity reaction to a constituent of the vaccine including meningococcal polysaccharide, diphtheria toxoid or the CRM197 carrier protein (Meningitec®, Menjugate®) or tetanus toxoid (NeisVac-C®) or any component or ingredient of the vaccine</li> <li>• Latex allergy (Only NeisVac-C is suitable for latex allergy)</li> <li>• Children under two months old – Please refer to the GP</li> <li>• Individuals with immunosuppression and HIV infection should be excluded from this PGD – Please refer to GP</li> <li>• Vaccination should be delayed in subjects suffering from an acute febrile illness. However, minor illnesses or infections without a fever or systemic upset are not a contraindication to vaccination and not a</li> </ul>

	<p>valid reason to postpone immunisation</p> <ul style="list-style-type: none"> <li>• Corticosteroids and immunosuppressive treatments may interfere with antibody production and cause failure of the vaccination. Patients on these groups of drugs should be excluded from this PGD – Please refer to the GP</li> <li>• The intradermal administration regimen for this vaccine is not covered by this PGD – Please refer to the GP</li> <li>• Pregnancy and lactation – Please refer to the GP</li> <li>• People over 5 years of age who have received the Meningococcal polysaccharide A,C, W, Y vaccine (e.g. for travel purposes) within the previous 3 years</li> <li>• NB Patients may be excluded by cautions or interactions</li> </ul> <ul style="list-style-type: none"> <li>• <i>When there is a doubt, appropriate advice should be sought from a consultant paediatrician, immunisation coordinator or consultant in communicable disease control, rather than withhold immunisation. Specialist advice must be sought on the vaccines and circumstances in which they could be given.</i></li> <li>• The risk to the individual of not being immunised must be taken into account. For further details please refer to the Green Book and the SPC as above and/or contact the manufacturer.</li> </ul>
<b>Action if excluded</b>	<ul style="list-style-type: none"> <li>• Offer advice on when individuals may have the vaccine.</li> <li>• Offer advice about disease avoidance and initial symptoms.</li> <li>• Reschedule or refer/transfer to the appropriate prescriber/service as soon as appropriate.</li> <li>• Discuss with patient/client and document the reasons for exclusion from treatment under the PGD.</li> </ul>
<b>Consent</b>	<p>The proposed treatment including the risks, benefits and side effects must be explained to the patient/client/guardian and verbal consent obtained and recorded in the notes.</p>
<b>Action if patient declines treatment</b>	<ul style="list-style-type: none"> <li>• Document refusal in notes.</li> <li>• Seek medical advice if necessary.</li> <li>• Refer/transfer to the GP if necessary.</li> <li>• Offer disease avoidance advice if travelling.</li> </ul>
<b>Handling / use / storage / labelling</b>	<ul style="list-style-type: none"> <li>• Vaccines should be stored in original packaging</li> <li>• Refrigerate at +2°C to +8°C. Do not freeze</li> <li>• Protect from light</li> <li>• 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</li> <li>• Shake before use</li> </ul>
<b>Reasons for referral or for seeking medical advice</b>	<ul style="list-style-type: none"> <li>• Exclusions or patient preference as above</li> <li>• Patients should be referred to a local specialist centre</li> <li>• Patients with asplenia or splenic dysfunction should also be offered Hib, pneumococcal and influenza vaccines (for use and administration of these vaccines please refer to the Green Book and related PGDs)</li> <li>• Emergency treatment of anaphylactic reactions – Guidelines for Healthcare Providers – Resuscitation Council (UK) available online at <a href="http://www.resus.org.uk/pages/reaction.pdf">http://www.resus.org.uk/pages/reaction.pdf</a> with the following algorithm <a href="http://www.resus.org.uk/pages/anaalgo.pdf">http://www.resus.org.uk/pages/anaalgo.pdf</a> .</li> <li>• If there are concerns or cautions/interactions relating to the vaccine to be given, practitioners should seek medical advice or refer/transfer to the appropriate prescriber/service if necessary.</li> </ul>

Description of Treatment	
<b>Name, form and strength of medicine</b>	<ul style="list-style-type: none"> <li>• <b>Menjugate Kit®</b> (Sanofi Pasteur MSD) <i>One dose (0.5ml of the reconstituted vaccine) contains: Neisseria meningitides group C (strain C11) oligosaccharide 10 micrograms, conjugated to corynebacterium diphtheriae CRM<sub>197</sub> protein 12.5 to 25.0 micrograms</i></li> <li>• <b>Meningitec®</b> vaccine (Wyeth) <i>One dose (0.5ml) contains: Neisseria meningitidis (strain C11) Serogroup C oligosaccharide 10 micrograms, conjugated to Cornebacterium diphtheriae CRM<sub>197</sub> carrier protein (approximately 15 micrograms)</i></li> <li>• <b>NeisVac-C®</b> vaccine (Baxter) <i>One dose (0.5ml) contains: Neisseria meningitidis group C (strain C11) polysaccharide (de-O-acetylated) 10 micrograms, conjugated to tetanus toxoid (10-20 micrograms)</i></li> </ul> <p><b>There is no data on the use of different Meningococcal serogroup C conjugate vaccines within the primary series for boosting. Whenever possible, the same vaccine should be used throughout.</b></p>
<b>Legal Classification</b>	POM (Prescription Only Medicine)
<b>Black Triangle▼</b>	No
<b>PGD covering use outside terms of Summary Product Characteristics (SPC)</b>	<p><b>YES</b> – Individuals with a bleeding disorder – vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding <b>AND</b> the MenC vaccines listed above are now licensed for use in a two-dose schedule from two months of age. Although the licence states that two doses should be given at least two months apart, evidence from UK studies shows that immunogenicity is adequate in children immunised at a one-month interval (Southern et al., 2006, cited in ‘The Green Book’).</p> <p>Please, explain to patient/client that advice differs from patient information leaflet and the reason for this.</p>
<b>Dose</b>	<p><b>Infants under one year of age:</b></p> <ul style="list-style-type: none"> <li>• First dose of 0.5ml of MenC vaccine</li> <li>• Second dose of 0.5ml of MenC vaccine, one month after the first dose</li> <li>• A third dose of Hib/MenC vaccine should be given between 13 months and 2 years to complete the course. (See appropriate PGD for this vaccine)</li> </ul> <p><b>Children from one year and adults under 25 years or other individuals at elevated risk regardless of age</b> The primary course of MenC containing vaccine for this age group is:</p> <ul style="list-style-type: none"> <li>• one dose of 0.5ml.</li> </ul>
<b>Route / method</b>	<ul style="list-style-type: none"> <li>• Intramuscular injection. The deltoid muscle is the preferred site of injection in adults and older children. Anterolateral thigh is preferred in younger children.</li> <li>• Deep subcutaneous route should be used for individuals with bleeding disorders</li> <li>• The vaccine should not be administered into the buttock or intradermally since this may result in a lower immune response.</li> <li>• Not to be administered intravenously</li> <li>• May be given concomitantly with other vaccines using separate sites</li> </ul>

	<p>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.</p>
<p><b>Frequency of administration</b></p>	<p><b><u>Primary Immunisation for infants under one year of age:</u></b></p> <ul style="list-style-type: none"> <li>• The primary course of MenC vaccination consists of two doses, with an interval of one month between each dose. <ul style="list-style-type: none"> <li>– The recommended age for vaccination is at three and four months of age</li> <li>– If the primary course is interrupted it should be resumed but not repeated</li> </ul> </li> </ul> <p>The currently available MenC vaccines are now licensed for use in a two-month schedule from two months of age. Although the licence stated that two doses should be given at least two months apart, evidence from UK studies shows that immunogenicity is adequate in children immunised at a one-month interval (Southern et al., 2006, cited in 'The Green Book').</p> <p><b><u>Primary Immunisation for children from one year of age and adults:</u></b></p> <ul style="list-style-type: none"> <li>• <b>The primary course of MenC vaccine for this age group is one dose.</b> <ul style="list-style-type: none"> <li>○ If the primary course in children under one year was not completed, then a single booster dose of Hib/MenC should be given, at least one month after the last dose.</li> </ul> </li> <li>• <b>All individuals under 25 years and other individuals at elevated risk, regardless of their age, should be immunised with a single dose of MenC.</b> <ul style="list-style-type: none"> <li>○ Any unprotected individual attending university, irrespective of age, should be immunised before they enrol or as soon as possible thereafter.</li> </ul> </li> </ul> <p><b><u>Reinforcing Immunisation:</u></b></p> <ul style="list-style-type: none"> <li>• <b>A reinforcing (booster) dose of Hib/MenC is recommended at 12 months of age for children who have received a complete primary course of two doses of MenC vaccine</b></li> </ul> <p><b>Please refer to the Green Book for further information regarding individuals of all age groups with unknown or incomplete vaccination histories.</b></p> <p><b>Use of Hib/MenC and MMR vaccines are out of the scope of this PGD. Please refer to the appropriate PGD to proceed with these recommendations.</b></p> <p><b>▼ Menveo ® is not covered by this PGD.</b></p> <p>For general guidance and further details please refer to the Green Book, BNF, SPC and/or contact the Manufacturer.</p>
<p><b>Duration of treatment</b></p>	<p>See above</p>
<p><b>Relevant warnings and Adverse Drug Reactions (ADRs)</b></p>	<ul style="list-style-type: none"> <li>• Pain, tenderness, swelling or redness at the injection site, and mild fevers are <u>common</u> in all age groups.</li> <li>• In infants and toddlers, crying, irritability, drowsiness, impaired sleep, reduced eating, diarrhoea and vomiting are <u>commonly seen</u>. In older children and adults, headaches, myalgia and drowsiness <u>may be seen</u>.</li> <li>• Neurological reactions such as dizziness, febrile/afebrile seizures, faints, numbness and hypotonia following MenC are <u>very rare</u>.</li> <li>• Confirmed anaphylaxis after immunisation is <u>extremely rare</u>, with anaphylactoid reactions reported approximately one in every 500,000 doses.</li> </ul>

	<p><b>Adverse Drug Reactions must be recorded and the patient's GP informed</b></p> <p><b>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</b></p> <p><b>For medicines showing the black triangle ▼ symbol ALL suspected ADRs should be reported via the Yellow Card reporting scheme</b></p>
<b>Drug Interactions</b>	<ul style="list-style-type: none"> <li>• None known</li> <li>• MenC vaccines should not be mixed with other vaccines in the same syringe</li> </ul>
<b>Advice to patient</b>	<ul style="list-style-type: none"> <li>• Administration and side effects to be discussed prior to immunisation</li> <li>• Temperature control and management of local reactions</li> <li>• Information on further contacts and out-of-hours services if later required</li> <li>• Provide a patient information leaflet if available</li> <li>• <b>Please advise patients that if they feel any symptom such as drowsiness, it may temporarily affect their ability to drive or use machines.</b></li> <li>• Please refer to the <b>Green Book</b> for further details (as above).</li> </ul>
<b>Records and follow up</b>	
<b>Follow-up and / or referral arrangements</b>	<ul style="list-style-type: none"> <li>• Next vaccination date is advised if appropriate</li> </ul>
<b>Details of records to be kept</b>	<ul style="list-style-type: none"> <li>• Record that valid informed consent was given</li> <li>• Name of patient, address, date of birth and GP</li> <li>• Name of member of staff who administered the vaccine</li> <li>• Date of treatment</li> <li>• Dose administered, site and route</li> <li>• Manufacturer of product, brand, batch number and expiry date</li> <li>• Advice given</li> <li>• Advice given if excluded or declines treatment</li> <li>• Record how the patient's central record or GP surgery record will be updated</li> <li>• Details of any ADRs and actions taken</li> </ul> <p>All records should be clear, legible and contemporaneous The information should be recorded as appropriate in</p> <ul style="list-style-type: none"> <li>• Patient-held record or Personal Child Health Record (PCHR, the Red Book) for children</li> <li>• Patient's GP record or other patient record, depending on location</li> <li>• Child Health Information System (CHIS)</li> <li>• GP practice computer system</li> </ul> <p><b>A computer or manual record of all individuals receiving treatment under this PGD should also be kept for audit purposes</b></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](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 (2011) chapter 14.4 available online at <http://bnf.org/bnf/bnf/current/> accessed 31.08.2011
- Department of Health (2006) "The Green Book" Immunisation Against Infectious Diseases plus update to chapter 22 : Meningococcal; available online at [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_079917](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 Menjugate Kit® Vaccine (Sanofi Pasteur MSD) available online at <http://www.medicines.org.uk/EMC/medicine/17873/SPC/Menjugate+Kit/> (last updated 21.12.2010) and accessed 31.08.2011
- Summary of Product Characteristics for Meningitec® Vaccine (Wyeth) available online at <http://www.medicines.org.uk/EMC/medicine/20747/SPC/Meningitec+in+pre-filled+syringe/> (last updated 18.07.2011) and accessed 31.08.2011
- Summary of Product Characteristics for NeisVac-C® Vaccine (Baxter) available online at [http://www.gsk.ca/english/docs-pdf/NeisVac-C\\_PM\\_20090121\\_EN.pdf](http://www.gsk.ca/english/docs-pdf/NeisVac-C_PM_20090121_EN.pdf) 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: .....
- 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.