Public Health England

Publications Gateway Reference: 2015184

PATIENT GROUP DIRECTION (PGD)

Administration of meningococcal group A, C, W and Y conjugate vaccine (MenACWY) to individuals eligible for national routine MenACWY vaccination programme; university freshers (catch-up); outbreak control and contacts of confirmed cases, for active immunisation against *Neisseria meningitidis*.

This PGD is for the administration of meningococcal group A, C, W and Y conjugate vaccine (MenACWY) by currently registered nurses.

Reference no:	MenACWY PGD
Version no:	v02.00
Valid from:	01 July 2017
Review date:	01 January 2019
Expiry date:	30 June 2019

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended.

Operation of this PGD is the responsibility of commissioners and service providers.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

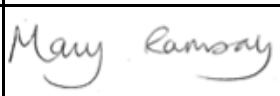
[1] This includes any relevant amendments to legislation (eg 2013 No235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
Version 01.00	New PHE PGD	10 July 2015
Version 02.00	PHE MenACWY PGD amended to: • remove specific information on individual catch-up cohorts from previous years • removal of preferred vaccine choice and related update to off-label section following changes to the Nimenrix® licence • reference the protocol for ordering storage and handling of vaccines • update wording regarding authorisation in line with agreed PHE PGD template changes • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	04 May 2017

1. PGD Template Development

This PGD template has been developed by the following on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		12/05/2017
Doctor	Mary Ramsay Consultant Epidemiologist and Head Immunisation, Hepatitis & Blood Safety Department, PHE		11/05/2017
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		12/05/2017

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by PHE Medicines Management Group and PHE Quality and Clinical Governance Steering Group.

Acknowledgements

Name	Designation
Dr Shamez Ladhani	Paediatric Infectious Disease Consultant, Public Health England
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Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager / Nurse Consultant, Public Health England / NHS England (Lancashire and South Cumbria)
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Sue Mulvenna	Head of Pharmacy, NHS England South West
Matthew Olley	Immunisation Manager, Public Health England / NHS England London Region
Lisa Rees	Medicines Management Pharmacist, Bristol Clinical Commissioning Group
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East

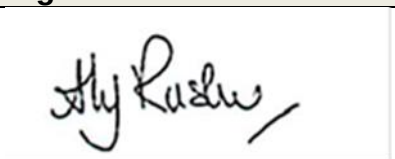
2. Organisational Authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS ENGLAND MIDLANDS AND EAST (CENTRAL MIDLANDS) authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
General medical practices from which NHS England Midlands and East (Central Midlands) commissions immunisation services
Limitations to authorisation
Practice staff are reminded that current contractual obligations may restrict administration of the vaccine(s) covered by this PGD to a more limited cohort of patients than that legally permitted by the inclusion criteria.

Organisational Approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director, NHS England Midlands and East (Central Midlands)	**Dr Aly Rashid**		**22nd May 2017**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to:

For Bedfordshire, Hertfordshire, Luton and Milton Keynes - england.immsqa@nhs.net - the (Central Midlands) South public health/screening and immunisation team

For Leicestershire, Lincolnshire and Northamptonshire – england.llimms@nhs.net - the (Central Midlands) North and Central public health/screening and immunisation team

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of Staff

Qualifications and professional registration required	Registered professional with one of the following bodies: • nurses currently registered with the Nursing and Midwifery Council (NMC)
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ("The Green Book"), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards for Immunisation Training (2005) • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the "cold chain" • must be competent in the recognition and management of anaphylaxis • must have access to the Patient Group Direction and associated online resources • should fulfil any additional requirements defined by local policy **THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies.

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals, detailed in the inclusion criteria, against *Neisseria meningitidis* group A, C, W and Y in accordance with the recommendations given in Chapter 22 of *Immunisation Against Infectious Disease: The Green Book.*
Criteria for inclusion	**Individuals who are:** • eligible for routine MenACWY immunisation ie whole birth cohort in school year 9 and/or 10 as per national recommendations and local delivery of concurrent adolescent immunisations including Td/IPV • eligible for routine MenACWY conjugate vaccine, ie born on or after 1 Sep 1996 and until their 25th birthday, who have missed the routine vaccination offering in year 9 or year 10, and have unknown or incomplete MenACWY vaccination history (Note: this includes individuals in catch-up cohorts) • aged 10 years to less than 25 years with an incomplete or unknown MenC vaccination history • prospective students up to 25 years of age who are entering university for the first time and who have not received a dose of MenACWY conjugate vaccine after their tenth birthday Note: Vaccination should be offered before they enrol or as soon as possible thereafter, ideally at least two weeks before attending university to ensure timely protection. • a close contact of a confirmed case of *Neisseria meningitidis* group A, C, W or Y disease • in a cohort recommended MenACWY immunisation following a local outbreak of *Neisseria meningitidis* and specific advice from Public Health England and the local Health Protection Team
Criteria for exclusion[2]	Individuals for whom no valid consent has been received Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of the vaccine • have had a confirmed anaphylactic reaction to any constituent or excipient of the vaccine, including diphtheria toxoid, CRM 197 carrier protein (Menveo®), tetanus toxoid (Nimenrix®) • have previously received MenACWY conjugate vaccine when over 10 years old, with the exception of contacts of confirmed *Neisseria meningitidis* group A, C, W or Y infection • are at increased risk of invasive meningococcal infection, ie with asplenia, splenic dysfunction or complement disorders (including those on complement inhibitor treatment ie eculizumab) – see MenACWY Risk Groups PGD • require vaccination for occupational health reasons eg laboratory workers working with meningococci • require vaccination for the purpose of travel • are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation)

[2] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

Cautions including any relevant action to be taken	Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.
Action to be taken if the patient is excluded	Individuals who have received MenACWY conjugate vaccine over the age of 10 years do not routinely require further MenACWY immunisation with the exception of contacts of confirmed Neisseria meningitidis group A, C, W or Y infection. Contacts should be offered an appropriate meningococcal sero-group containing vaccine if not received in the preceding 12 months. Individuals who are at increased risk of invasive meningococcal infection, ie with asplenia, splenic dysfunction or complement disorders (including those on complement inhibitor treatment ie eculizumab), should be vaccinated in accordance with recommendations in Chapter 7 of Green Book (see MenACWY Risk Groups PGD). Individuals requiring vaccination for occupational health reasons, eg laboratory workers working with meningococci, should be referred to their occupational health service provider for vaccination. Individuals requiring vaccination solely for the purpose of travel are not covered by this PGD and should be referred to, or immunised as part of, a travel immunisation service. MenACWY vaccine is not available on the NHS for the purpose of travel. In case of postponement due to acute severe febrile illness advise when the patient may be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the patient of not being immunised must be taken into account. Document reason for exclusion and any action taken in patient's clinical records. In a GP practice setting, inform or refer to the GP or prescriber as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent, from the patient or a person legally able to act on the patient's behalf, must be obtained for each administration. Advise individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and the decision reached. In a GP practice setting, inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of Treatment

Name, strength & formulation of drug	**Menveo**®, 0.5ml reconstituted vaccine solution containing: Originally contained in powder vial: Meningococcal group A oligosaccharide[1] 10micrograms Originally contained in the solution vial: Meningococcal group C oligosaccharide[1] 5 micrograms Meningococcal group W135 oligosaccharide[1] 5 micrograms Meningococcal group Y oligosaccharide[1] 5 micrograms [1]conjugated to *Corynebacterium diphtheriae* CRM_{197} protein Or **Nimenrix**®**,** 0.5ml reconstituted vaccine solution containing: Originally in powder: *Neisseria meningitidis* A polysaccharide[2] 5 micrograms *Neisseria meningitidis* C polysaccharide[2] 5 micrograms *Neisseria meningitidis* W135 polysaccharide[2] 5 micrograms *Neisseria meningitidis* Y polysaccharide[2] 5 micrograms [2] conjugated to tetanus toxoid carrier protein 44 micrograms Solvent for solution for injection in pre-filled syringe
Legal category	Prescription Only Medicine (POM).
Black Triangle▼	No
Off-label use	Administration by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 of "The Green Book". Menveo® is off-label for children under 2 years of age. Nimenrix® is licensed from 6 weeks of age for a schedule with a two month interval between doses, but a one-month interval is in accordance with the advice in Chapter 22 of "The Green Book". Either vaccine is recommended in accordance with the advice in Chapter 22 of "The Green Book". Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration Continued over page	The MenACWY vaccines must be reconstituted in accordance with the manufacturers' instructions prior to administration. Following reconstitution, MenACWY conjugate vaccine should be given as a single 0.5ml dose by intramuscular injection, preferably in the deltoid region of the upper arm. The anterolateral aspect of the thigh is the preferred site for infants under one year old. The MenACWY conjugate vaccines must not be given intravascularly or intradermally. For individuals with a bleeding disorder, vaccines normally given by an IM route should be given by deep subcutaneous injection to reduce the risk of bleeding (see "The Green Book" Chapter 4). When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the

Route / method of administration (continued)	vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. The vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect before reconstitution and following reconstitution prior to administration. In the event of either being observed, discard the vaccine. It is recommended that the vaccine be administered immediately after reconstitution, to minimize loss of potency. Discard reconstituted vaccine if it is not used within 8 hours (see Storage section). The SPCs for Menveo® and Nimenrix® provide further guidance on reconstitution and administration and are available from the electronic Medicines Compendium website: www.medicines.org.uk
Dose and frequency of administration	**Aged 12 months and over** Single 0.5ml dose of either Menveo® or Nimenrix® vaccine. Note: Unless they are confirmed to have been immunised against the relevant meningococcal sero-group within the preceding 12 months, vaccination should be offered to close contacts of any age. **Contacts aged under 12 months** Two 0.5ml doses administered at least 4 weeks apart (see Off-label section)
Duration of treatment	Single dose of 0.5ml (repeated at least 4 weeks later in children under 12 months of age).
Quantity to be supplied / administered	Single dose of 0.5ml.
Supplies	Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for the national immunisation programme are provided free of charge. Vaccines for private prescriptions, occupational health use or travel, are NOT provided free of charge and should be ordered from the manufacturers. Vaccine for the national immunisation programme should not be used for the vaccination of at risk individuals, contacts of confirmed cases and in outbreaks of MenACWY infection. Vaccine should be ordered from the manufacturer. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
Storage	Store between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. After reconstitution, the vaccine should be used immediately. However, stability after reconstitution has been demonstrated for 8 hours below 25°C (below 30°C for Nimenrix®). Discard any reconstituted vaccine not used within 8 hours.

Disposal	Equipment used for immunisation, including used vials, ampoules, or syringes, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug Interactions	Immunological response may be diminished in individuals receiving immunosuppressant treatment. This is **not** a reason to withhold vaccination but the patient/their carer should be advised. Meningococcal vaccines can be given at the same time as other vaccines such as the pneumococcal conjugate vaccine, measles, mumps and rubella (MMR), diphtheria, tetanus, pertussis, polio, Hib and HPV where indicated. A detailed list of interactions associated with Menveo® or Nimenrix® is available in the SPC for the vaccine, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & Management of Adverse Reactions	**Menveo®** The most common adverse reactions observed after administration of Menveo® vaccine are drowsiness, malaise, headache, nausea, irritability and injection site pain, erythema and induration. Fever, chills, nausea, vomiting, diarrhoea, eating disorders, myalgia, arthralgia and rash are also listed as common side effects. **Nimenrix®** The most common adverse reactions observed after administration of Nimenrix® vaccine are drowsiness, fatigue, headache, loss of appetite, irritability, fever and injection site pain, erythema and induration. Gastro-intestinal symptoms (including nausea, vomiting and diarrhoea) and injection site haematoma are also listed as common side effects. A detailed list of adverse reactions associated with Menveo® or Nimenrix® is available in the SPC for the vaccine, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of Adverse Reactions	Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Any adverse reaction to the vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: eg For parents of 'contact' children under 12 months: • Why is my child being offered an 'off-label' vaccine. Available from: www.gov.uk/government/collections/immunisation

Patient advice /Follow up treatment	Menveo® or Nimenrix® will only confer protection against *Neisseria meningitidis* group A, C, W and Y. The vaccine will not protect against any other *Neisseria meningitidis* groups. Individuals should continue to seek prompt medical attention at the first signs of possible meningitis infection. Inform patient/carer of possible side effects and their management. The patient/carer should be advised to seek medical advice in the event of a severe adverse reaction. When applicable, advise patient/carer when the subsequent dose is due. When administration is postponed advise the patient when to return for vaccination.
Special Considerations / Additional Information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone. Each brand of vaccine uses a different carrier protein and the healthcare professional should refer to the SPC supplied with the vaccine if there has been a previous hypersensitivity reaction to vaccination. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. Meningococcal vaccines may 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 virus or bacterial vaccines or toxoids.
Records Continued over page	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled immunisers record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed. The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate

Records (continued)	documentation/pathway when vaccine is administered to individuals under 19 years of age. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key References

Key references	**MenACWY Conjugate Vaccine** • Nimenrix® Summary of Product Characteristics. GlaxoSmithKline UK Updated 21 December 2016 http://www.medicines.org.uk/emc/medicine/26514 • Menveo® Summary of Product Characteristics. Novartis Vaccines Updated 09 October 2015 http://www.medicines.org.uk/emc/medicine/27347 • Immunisation Against Infectious Disease: The Green Book, Chapter 22 last updated 20 September 2016. https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22 • Meningococcal ACWY (MenACWY) vaccination programme. Published 07 November 16 https://www.gov.uk/government/collections/meningococcal-acwy-menacwy-vaccination-programme • Meningococcal Disease: Guidance, Data and Analysis. Published 28 August 2015 https://www.gov.uk/government/collections/meningococcal-disease-guidance-data-and-analysis • Enhanced Service Specification: Meningococcal ACWY (MenACWY) 18 years on 31 August vaccination programme 2017/18. Published March 2017 https://www.england.nhs.uk/publication/enhanced-service-specifications/ **General** • PHE Immunisation Collection. https://www.gov.uk/government/collections/immunisation • British National Formulary (BNF) and British National Formulary for Children (BNF-C) www.bnf.org https://www.evidence.nhs.uk/formulary/bnf/current • National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published August 2013 https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014 https://www.nice.org.uk/guidance/mpg2/resources • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336 • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste

7. Multiple practitioner authorisation sheet

MenACWY PGD v02.00 Valid from: 01/07/2017 Expiry: 30/06/2019

Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of _____ **(INSERT NAME OF ORGANISATION)** for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.