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Meningococcal Group A, C, W, and Y (MenACWY) Conjugate Vaccine for Risk Groups Patient Group Direction (PGD)

This PGD is for the administration of meningococcal group A, C, W, and Y conjugate vaccine (MenACWY) to individuals with an underlying medical condition which puts them at increased risk from *Neisseria meningitidis*.

This PGD is for the administration of MenACWY conjugate vaccine by registered healthcare practitioners identified in <u>section 3</u>, subject to any limitations to authorisation detailed in <u>section 2</u>.

Reference no: MenACWY Risk Groups PGD

Version no: v5.0

Valid from: 31 July 2025 Review date: 30 June 2027

Expiry date: 31 December 2027

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England, 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). Sections 2 and 7 can be edited within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

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 the UKHSA PGD templates for authorisation can be found from:

MenACWY Risk Groups PGD v5.0 Valid from: 31 July 2025 Expiry: 31 December 2027

¹ This includes any relevant amendments to legislation.

Immunisation patient group direction (PGD) templates

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Vaccination Team, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- · Leicester, Leicestershire and Rutland
- Northamptonshire
- · Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

Change history

Version number	Change details	Date
v1.0	New MenACWY Risk Groups PHE PGD Template	1 February 2017
v2.0	MenACWY Risk Groups PGD amended to:	21 December 2018
	 include additional healthcare practitioners in Section 3 remove black triangle for Nimenrix® insert paragraph regarding coeliac disease refer to vaccine incident guidelines in off-label and storage sections include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	
v3.0	MenACWY Risk Groups PGD amended to:	28 January 2021
	 express dose interval in weeks and remove specific reference to Hib/MenC in line with Chapter 7 include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates 	
v4.0	MenACWY Risk Groups PGD amended to:	30 January 2023
	 include particulars pertaining to an additional licensed ACWY vaccine (MenQuadfi[®]) 	
	 amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 	
	 include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs 	
	 replace Public Health England' and 'PHE' with 'UKHSA' including branding and updated contact details 	
v5.0	MenACWY Risk Groups PGD amended to:	2 June 2025
	take account of the forthcoming changes to the childhood immunisation schedule, pending withdrawal of Hib/MenC (Menitorix®)	
	include minor formatting and other revisions to bring the template in line with other UKHSA PGD templates	
	correct spelling errors to MenQuadfi® from v4.0	
	reflect updated references	
	 include registered healthcare professionals named in both the Additional Roles Reimbursement Scheme (ARRS) and <u>HMR2012</u> 	

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist - Immunisation Programmes, UKHSA	Cluchum	23 May 2025
Doctor	Professor Shamez Ladhani Paediatric Infectious Diseases Consultant, Professor of Paediatric Infections and Vaccinology, St George's University London and Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA	Sadhani	23 May 2025
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisation Programmes, UKHSA	DGieen.	23 May 2025

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee.

Expert Panel

Name	Designation
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Jess Baldasera	Health Protection Practitioner, North East Health Protection Team, Regions Directorate, UKHSA
Helen Beynon	Clinical Advisor, Immunisation Clinical Advice Response Service (CARS), NHSE London
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Advanced Specialist Pharmacist, Medicines Governance (Patient Group Directions and Medicines Mechanisms), NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Shilan Ghafoor	Medicines Governance Pharmacist, Medicines Governance, UKHSA
Greta Hayward	Consultant Midwife – Immunisation Programmes, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Elizabeth Luckett	Senior Screening & Immunisation Manager, Screening and Immunisation Team – Kent and Medway, NHSE South East
Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA
Briony Mason	Vaccination Manager, NHSE West Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London

MenACWY Risk Groups PGD v5.0 Valid from: 31 July 2025 Expiry: 31 December 2027 Page 4 of 17

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.

NHSE - Midlands authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services

Primary care services and/or all organisations commissioned or contracted by NHS England – Midlands to provide immunisation services in:

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire, and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire
- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford, and Wrekin
- Black Country

Limitations to authorisation

None

Coventry and Warwickshire

Organisational approval (le	gal requirement)		
Role	Name	Sign	Date
Regional Director of Commissioning, NHS England Midlands	Roz Lindridge	I haid	06/06/2025

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

Local enquiries regarding the use of this PGD may be directed to Vaccination Team, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- · Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- · Coventry and Warwickshire

<u>Section 7</u> 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.

MenACWY Risk Groups PGD v5.0 Valid from: 3

3. Characteristics of staff

Qualifications and professional registration

All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the <u>additional requirements</u> and <u>continued training requirements</u> to ensure their competency is up to date, as outlined in the sections below.

Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: this PGD is not relevant to privately provided community pharmacy services)
- dieticians, occupational therapists, paramedics, physiotherapists and podiatrists currently registered with the Health and Care Professions Council (HCPC)

Check <u>section 2</u> (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.

Additional requirements

Additionally, practitioners:

- must be authorised by name as an approved practitioner under the current terms of this PGD 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 <u>NICE competency framework for</u> health professionals using PGDs)
- 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 <u>National Minimum Standards and Core Curriculum for</u> <u>Immunisation Training</u>
- 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 intramuscular injection technique
- must be competent in the recognition and management of anaphylaxis
- must have access to the PGD 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 the UKHSA, NHS England (NHSE) 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 with an underlying medical condition which puts them at increased risk from <i>Neisseria meningitidis</i> groups A, C, W and Y, in accordance with the recommendations given in Chapter 7 and Chapter 22 of Immunisation Against Infectious Disease: the Green Book.	
Criteria for inclusion	Individuals who: • are at increased risk of invasive meningococcal infection with asplenia, splenic dysfunction, or complement disorders (including those on, or due to commence complement inhibitor treatment, such as eculizumab (Soliris®) and ravulizumab (Ultomiris®)	
	Note: This includes individuals with medical conditions accompanied by functional hyposplenism (such as sickle cell disease), but does not include those with coeliac disease unless concurrent hyposplenism has been diagnosed.	
Criteria for exclusion ²	Individuals for whom no valid consent has been received (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). For further information on consent, see Chapter 2 of the Green Book. Several resources are available to inform consent (see written information to be given to individual or carer section).	
	 Individuals who: have had a confirmed anaphylactic reaction to a previous dose of the vaccine or to any constituent or excipient of the vaccine, including diphtheria toxoid, CRM₁₉₇ carrier protein (Menveo®) and tetanus toxoid (Nimenrix® and MenQuadfi®) have received MenACWY conjugate vaccine over 1 year of age and in the last 12 months (excluded as they are adequately immunised) 	
	 are not at increased risk of invasive meningococcal infection and require routine MenACWY vaccination are a contact of an individual diagnosed with <i>Neisseria meningitidis</i> groups A, C, W and Y disease. 	
	 require vaccination for occupational health reasons such as laboratory workers working with meningococci require vaccination for the purpose of travel 	
	 are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) 	
Cautions, including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see <u>Chapter 8</u> of the Green Book and advice issued by the <u>Resuscitation Council UK</u>).	
	The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with national recommendations.	
	Where possible, vaccines should be administered 2 weeks before immunosuppressive treatment begins, before immunosuppression occurs, or deferred until an improvement in immunity is seen.	
	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.	

 $^{^2}$ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

MenACWY Risk Groups PGD v5.0 Valid from: 31 July 2025 Expiry: 31 December 2027 Page 8 of 17

Action to be taken if the individual is excluded

Individuals who have had a confirmed anaphylactic reaction to a previous dose of the vaccine or any of its components should be referred to a clinician for specialist advice and appropriate management.

Individuals who have received MenACWY conjugate vaccine over one year of age and in the last 12 months do not require a further dose of MenACWY conjugate vaccine when diagnosed at risk.

Individuals who are not at increased risk of invasive meningococcal infection and require routine MenACWY vaccination or who are a contact of Neisseria meningitidis groups A, C, W and Y disease, should be vaccinated in accordance with UKHSA recommendations (see MenACWY PGD).

Individuals requiring vaccination for occupational health reasons, such as 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 private travel immunisation service. MenACWY conjugate 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 individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity.

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 individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in the individual's clinical records.

Inform or refer to the individual's GP or a prescriber as appropriate.

Action to be taken if the individual or carer declines treatment

Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book.

Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Document the advice given and the decision reached.

Inform or refer to the individual's GP or a prescriber as appropriate.

Arrangements for referral for medical advice

As per local policy

MenACWY Risk Groups PGD v5.0

5. Description of treatment

Name, strength and formulation of	Meningococcal group A, C, W and Y conjugate vaccine, MenACWY:		
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 oligosaccharide¹ Meningococcal group W135 oligosaccharide¹ Meningococcal group Y oligosaccharide¹ ¹conjugated to Corynebacterium diphtheriae CRM₁₉₇ 	5 micrograms 5 micrograms 5 micrograms protein	
	or		
	Nimenrix®, 0.5ml reconstituted vaccine solution con	ntaining:	
	Originally in powder: • Neisseria meningitidis A polysaccharide² • Neisseria meningitidis C polysaccharide² • Neisseria meningitidis W135 polysaccharide² • Neisseria meningitidis Y polysaccharide² ² conjugated to tetanus toxoid carrier protein solvent for solution for injection in pre-filled syringe	5 micrograms 5 micrograms 5 micrograms 5 micrograms 44 micrograms	
	or		
	MenQuadfi®, 0.5ml solution for injection containing:		
	 Neisseria meningitidis group A polysaccharide³ Neisseria meningitidis group C polysaccharide³ Neisseria meningitidis group W polysaccharide³ Neisseria meningitidis group Y polysaccharide³ ³ conjugated to tetanus toxoid carrier protein 	10 micrograms 10 micrograms 10 micrograms 10 micrograms 55 micrograms	
Legal category	Prescription only medicine (POM)		
Black triangle▼	MenQuadfi [®] . As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product. All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme.		
Off-label use (continued over	disorder is off-label administration in line with advice in Chanter 4		
page)	Menveo® is off-label for children under 2 years of age, as is MenQuadfi® for children under 12 months.		
	Nimenrix® is licensed from 6 weeks of age, for a schedule with a minimum 2 month interval between doses, but a one month interval is in accordance with the advice in Chapter 22 of the Green Book.		
	Where possible, administer a vaccine licensed for the age of the individual licenced vaccine is available, then an alternative vaccine may be given on to avoid undue delay. All vaccines are recommended in accordance with advice in Chapter 22 of the Green Book.		
Vaccines should be stored according to the conditions detailed in the stored section below. However, in the event of an inadvertent or unavoidable d			

Off-label use

(continued)

of these conditions, refer to <u>Vaccine Incident Guidance</u>. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.

Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual, parent or carer that the vaccine is being offered in accordance with national guidance but outside of product licence.

Route and method of administration

MenACWY conjugate vaccines should be given as a single 0.5ml dose by intramuscular injection, preferably into the deltoid muscle 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 and must not be mixed with other vaccines in the same syringe.

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 vaccinations. The vaccines should be given at separate sites, preferably into different limbs. If given into 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.

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician familiar with the individual's bleeding risk, vaccine or similar small volume intramuscular injections can be administered with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or other treatment is administered. A fine needle (equal to 23 gauge or finer calibre, such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection.

For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by the intramuscular route should be given by deep subcutaneous injection, in accordance with the recommendations in the Green Book Chapter 4.

The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and discard the vaccine in accordance with local procedures.

The <u>SPC</u>s for Menveo[®], Nimenrix[®] and MenQuadfi[®] provide further guidance on preparation and administration.

Dose and frequency of administration

Individuals first diagnosed or presenting under one year of age

Individuals, with asplenia, splenic dysfunction or complement disorders, should receive:

- 2 primary doses of MenACWY vaccine at least 4 weeks apart during their first year, and
- one booster dose of MenACWY vaccine after the first birthday

(continued over page)

Where possible, the course should be completed with the same brand of MenACWY vaccine. However, vaccination should not be delayed and any of the licensed vaccines may be used.

Dose and	Individuals first diagnosed or presenting over one year of age
frequency of administration (continued)	Individuals over one year of age, with asplenia, splenic dysfunction or complement disorders, require a single dose of MenACWY vaccine on presentation, at least 4 weeks after vaccination with Hib/MenC (as applicable to individuals born on or before 30 June 2024).
	Refer to the Green Book <u>Chapter 7</u> for a practical schedule for immunising individuals with asplenia, splenic dysfunction or complement disorders, which takes into account the other vaccines required by these individuals.
Duration of treatment	See <u>dose and frequency of administration</u> section above
Quantity to be supplied and administered	Single dose of 0.5ml per administration
Supplies	Vaccine for the national immunisation programme should not be used for the vaccination of at-risk individuals. Vaccines should be ordered from the manufacturer or their wholesalers.
	Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging to protect from light.
	Do not freeze.
	In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance .
	After reconstitution of Menveo® and Nimenrix®, 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.
	MenQuadfi [®] and Nimenrix [®] stability data indicate the unopened vaccine may be used up to 72 hours following exposure to temperatures up to 25°C. See the respective SPC for further information.
	Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal. Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local waste disposal arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste.
Drug interactions	The immunological response may be diminished in individuals receiving immunosuppressant treatment. Vaccination is recommended even if the antibody response may be limited.
(continued over page)	MenACWY vaccine may be given at the same time as other vaccines. Where applicable, an interval of at least 4 weeks should be observed between Hib/MenC and MenACWY vaccination, to further boost immune response to the

MenACWY Risk Groups PGD v5.0 Valid from: 31 July 2025 Expiry: 31 December 2027 Page 12 of 17

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Drug interactions (continued)	MenC component. A detailed list of drug interactions associated with Menveo [®] , Nimenrix [®] and MenQuadfi [®] are available from the product's <u>SPC</u> .
Identification and management of adverse reactions	Menveo® The most common adverse reactions observed after administration of Menveo® vaccine are drowsiness, malaise, headache, 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, irritability, fever and injection site pain, erythema and induration and loss of appetite.
	Gastro-intestinal symptoms (including nausea, vomiting and diarrhoea) and injection site haematoma are also listed as common side effects.
	MenQuadfi [®]
	The most common adverse reactions observed after administration of MenQuadfi® vaccine are malaise, headache, myalgia and injection site pain. Fever and injection site induration and erythema are also listed as common side effects.
	A detailed list of adverse reactions associated with Menveo®, Nimenrix® and MenQuadfi® are available from the product's SPC .
Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the <u>Yellow Card reporting scheme</u> or by searching for MHRA Yellow Card in the Google Play or Apple App Store.
	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	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.
individual or carer	For resources in accessible formats and alternative languages, please visit Home – Health Publications.
	Immunisation promotional material may be provided as appropriate: • splenectomy leaflet
	Where applicable, inform the individual or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC .
Advice and follow up treatment	Menveo®, Nimenrix® or MenQuadfi® will only confer protection against <i>Neisseria meningitidis</i> group A, C, W and Y. The vaccine will not protect against any other <i>Neisseria meningitidis</i> groups. Individuals should continue to seek prompt medical attention at the first signs of possible meningitis or septicaemia.
	Inform the individual, parent or carer of possible side effects and their management.
(continued over	The individual, parent or carer should be advised to seek medical advice in the event of a severe adverse reaction and report this via the <u>Yellow Card reporting scheme</u> .
page)	When applicable, advise the individual, parent or carer when a subsequent dose is due.

MenACWY Risk Groups PGD v5.0 Valid from: 31 July 2025 Expiry: 31 December 2027

Page 13 of 17

Advice and follow When administration is postponed, advise the individual, parent or carer when to return for vaccination. up treatment (continued) Special Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 considerations and injection and access to a telephone at the time of vaccination. additional Medical conditions such as coeliac disease, sickle cell disease and other information haemoglobinopathies may be accompanied by functional hyposplenism. However, hyposplenism in coeliac disease is uncommon in children, and the prevalence correlates with the duration of exposure to gluten. Therefore, individuals diagnosed with coeliac disease early in life and well managed are unlikely to require additional MenACWY vaccine. Only those with known splenic dysfunction should be vaccinated in accordance with this PGD. Individuals receiving complement inhibitor therapy (for example, eculizumab, ravulizumab) are at heightened risk of meningococcal infection and should be vaccinated with both MenACWY and MenB vaccines (see MenB Risk Groups PGD), ideally at least 2 weeks prior to commencement of therapy. 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 breastfeeding with inactivated virus or bacterial vaccines or toxoids Each brand of vaccine uses a different carrier protein and the healthcare professional should refer to the SPCs supplied with the vaccine if there has been a previous hypersensitivity reaction to vaccination. Impact of changes to the childhood immunisation programme from 1 July 2025 Note that Hib/MenC will not be routinely offered to children turning 1 year of age on or after 1 July 2025, with a date of birth on or after 1 July 2024. The Hib/MenC vaccine is no longer expected to be in circulation beyond April 2026 and may be offered to children born on or before 30 June 2024 until all supplies

of the Hib/MenC vaccine have been exhausted. Practitioners should remain vigilant to the possibility that a young child may have been immunised with Hib/MenC beyond 1 July 2025 or that they remain eligible to receive the vaccine. Where applicable, advise the parent or legal guardian that a minimum interval of 4 weeks is preferable before the Hib/MenC dose is given to further boost immune response to the MenC component. If there is a concern that the child may be lost to follow-up, both vaccines may be given together. See the Hib/MenC PGD

Records

The practitioner must ensure the following is recorded:

- that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the Mental Capacity Act 2005
- name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP)
- · 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 immunisation declined

(continued over

page)

Records (continued)

- details of any adverse drug reactions and actions taken
- supplied via PGD

Records should be signed and dated (or a password-controlled immuniser's 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.

When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Services team (CHIS) using the appropriate documentation or pathway as required by any local or contractual arrangement.

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. Pfizer Ltd, updated 18 December 2024 http://www.medicines.org.uk/emc/medicine/26514
- Menveo[®] Summary of Product Characteristics. GlaxoSmithKline UK, updated 14 March 2025 https://www.medicines.org.uk/emc/medicine/27347
- MenQuadfi[®] Summary of Product Characteristics. Sanofi, updated 19 December 2024 https://www.medicines.org.uk/emc/product/12818/
- Immunisation Against Infectious Disease: The Green Book, <u>Chapter 22</u>, last updated 17 May 2022 and <u>Chapter 7</u>, last updated 10 January 2020 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Changes to the routine childhood schedule letter, published 30 April 2025 https://www.gov.uk/government/publications/changes-to-the-routine-childhood-schedule-letter

General

- NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/
- National Minimum Standards and Core Curriculum for Immunisation Training. Published 7 February 2018 https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions, published 27 March 2017 https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources
- UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation
- Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

MenACWY Risk Groups PGD v5.0 Valid from: 31 July 2025 Expiry: 31 December 2027

Before signing this patient group direction (PGD), check that the document has had the necessary authorisations in <u>section 2</u>. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD 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 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 PGD 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.