UK Health Security Agency

NHS

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Meningococcal Group A, C, W, and Y 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 vaccine by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	MenACWY Risk Groups PGD
Version no:	v04.00
Valid from:	28 February 2023
Review date:	1 September 2024
Expiry date:	28 February 2025

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England 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 within the designated editable fields provided.

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:
https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

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

[1] This includes any relevant amendments to legislation.

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

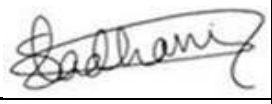
- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

Change history

Version number	Change details	Date
V01.00	New MenACWY Risk Groups PHE PGD Template	1 February 2017
V02.00	MenACWY Risk Groups PGD amended to: • 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	21 December 2018
V03.00	MenACWY Risk Groups PGD amended to: • 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	28 January 2021
V4.00	MenACWY Risk Groups PGD amended to: • include particulars pertaining to an additional licensed ACWY vaccine (MedQuadfi®) • 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	30 January 2023

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 and Vaccine Preventable Diseases Division, UKHSA		30 January 2023
Doctor	Dr Shamez Ladhani Paediatric Infectious Diseases Consultant, UKHSA		30 January 2023
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisation and Vaccine Preventable Diseases Division, UKHSA		30 January 2023

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

Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingam	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHS England (NHSE)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead, Southbourne Surgery
Jacqueline Lamberty	Lead Pharmacist, Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Mary Ramsay CBE	Director of Public Health Programmes, UKHSA
Elizabeth Luckett	Senior Screening & Immunisation Manager NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSE South West
Lesley McFarlane	Lead Immunisation Nurse Specialist Immunisation and Vaccine Preventable Diseases Division, UKHSA
Gill Marsh	Principal Screening and Immunisation Manager, NHSE North West
Tushar Shah	Lead Pharmacy Advisor, NHSE London

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 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 • Coventry and Warwickshire
Limitations to authorisation
None.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Regional Director of Commissioning NHS England - Midlands	**Roz Lindridge**		**16/02/2023**

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

Local enquiries regarding the use of this PGD may be directed to Vaccination and Screening Programmes, 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

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	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Section 2 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 NICE Competency framework for 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 National Minimum Standards and Core Curriculum for Immunisation Training • 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 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, 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 *Neisseria meningitidis* 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 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, CRM_{197} 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) • presenting at one year to under 2 years of age and have had a dose of Hib/ MenC in the last 8 weeks • are not at increased risk of invasive meningococcal infection and require routine MenACWY vaccination • are a contact of an individual diagnosed with *Neisseria meningitidis* 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 (continued over page)	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council UK. 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

[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

Cautions including any relevant action to be taken (continued)	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 1 year of age and in the last 12 months do not require a further dose of MenACWY conjugate vaccine when diagnosed at risk. Individuals aged 1 year of age should receive MenACWY vaccine at least 8 weeks after their Hib/MenC vaccine. 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 should be referred to the appropriate travel immunisation service. MenACWY vaccine is not available on the NHS for the purpose of travel. Individuals suffering from acute severe febrile illness should postpone immunisation until they have recovered. Immunisers should advise when the individual can 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 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 patient 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. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document 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

5. Description of treatment

Name, strength and formulation of drug	Meningococcal group A, C, W and Y conjugate vaccine, MenACWY: **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 or **MedQuadfi®**, 0.5ml solution for injection containing: • *Neisseria meningitidis* group A polysaccharide[3] 10 micrograms • *Neisseria meningitidis* group C polysaccharide[3] 10 micrograms • *Neisseria meningitidis* group W polysaccharide[3] 10 micrograms • *Neisseria meningitidis* group Y polysaccharide[3] 10 micrograms [3] conjugated to tetanus toxoid carrier protein 55 micrograms
Legal category	Prescription only medicine (POM)
Black triangle▼	MedQuadfi®. 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 page)	Administration by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 22 of 'The Green Book'. 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. Where possible, administer a vaccine licensed for the age of the individual. If no licenced vaccine is available, then an alternative vaccine may be given off-label to avoid undue delay. All vaccines are recommended in accordance with advice in Chapter 7 and Chapter 22 of 'The Green Book'. Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to Vaccine Incident

Off-label use (continued)	Guidance. Where vaccine is 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, consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route and method of administration	Menveo® and Nimenrix® must be reconstituted in accordance with the manufacturer's instructions prior to administration. All components of these vaccines should be visually inspected before and after reconstitution. It is recommended that these vaccines are administered immediately after reconstitution, to minimise loss of potency. Discard reconstituted vaccine if it is not used within 8 hours All vaccines should be inspected immediately prior to administration. In the event of observing any foreign particulate matter or difference in expected physical appearance of either the vaccine components or final product, discard the vaccine (see Storage section). 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 and must not be mixed with other vaccines in the same syringe. 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 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 SPCs for Menveo®, Nimenrix® and MenQuadfi® provide further guidance on vaccine handling and administration and are available from the electronic Medicines Compendium.
Dose and frequency of administration (continued over page)	**Individuals first diagnosed or presenting under 1 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. This dose should be administered at least 8 weeks after the routine vaccines scheduled at 1 year of age, to further boost the immune response to the MenC component of Hib/MenC. 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 frequency of administration (continued)	**Individuals first diagnosed or presenting over 1 year of age** Individuals over 1 year of age, with asplenia, splenic dysfunction or complement disorders, require a single dose of MenACWY vaccine on presentation, at least 8 weeks after vaccination with Hib/MenC. Refer to Green Book Chapter 7 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 dose 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. Vaccine should be ordered from the manufacturer. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Storage	Store between +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, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed 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® stability data indicates the vaccine may be used up to 72 hours following exposure to temperatures up to 25°C.
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 authority arrangements and NHSE guidance (HTM 07-01): Management and disposal of healthcare waste.
Drug interactions	Immunological response may be diminished in individuals receiving immunosuppressant treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines.
Identification and management of adverse reactions (continued over page)	**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.

Identification and management of adverse reactions (continued)	**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. **MedQuadfi®** 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 in the SPCs for the vaccines, which are available from the electronic Medicines Compendium.
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 scheme or 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 patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • Splenectomy leaflet
Patient advice and follow up treatment	Menveo®, Nimenrix® or MenQuadfi® 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 or septicaemia. Inform the individual, parent or carer of possible side effects and their management. The individual, parent or carer should be advised to seek medical advice in the event of a severe adverse reaction. When applicable, advise the individual, parent or carer when a subsequent dose is due. When administration is postponed, advise the individual, parent or carer when to return for vaccination.
Special considerations and additional information (continued over page)	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Medical conditions such as coeliac disease, sickle cell disease and other 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.

Special considerations and additional information (continued)	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 breast-feeding 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.
Records	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 immunisation declined • 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. The local Child Health Information Services team (Child Health Records Department) must be notified using the appropriate documentation/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 30 May 2022. http://www.medicines.org.uk/emc/medicine/26514 • Menveo® Summary of Product Characteristics. GlaxoSmithKline UK Updated 17 December 2021.https://www.medicines.org.uk/emc/medicine/27347 • MenQuadfi® Summary of Product Characteristics. Sanofi Pasteur. Updated 21 March 2022. https://www.medicines.org.uk/emc/product/12818/ • Immunisation Against Infectious Disease: The Green Book, Chapter 22, last updated 17 May 2022 and Chapter 7, last updated 10 January 2020. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book **General** • NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. 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 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 March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. 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. Updated July 2022. https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

MenACWY Risk Groups PGD v04.00 Valid from: 28 February 2023 Expiry: 28 February 2025

Before signing this patient group direction (PGD), check that the document has had the necessary authorisations in section 2. 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.