UK Health Security Agency

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

This PGD is for the administration of meningococcal groups A, C, W and Y conjugate vaccine (MenACWY) to individuals eligible for the national routine MenACWY vaccination programme or identified as a contact of a case of invasive meningococcal disease, in accordance with the Green Book and Guidance for Public Health Management of Meningococcal Disease in the UK.

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

Reference no:	MenACWY PGD
Version no:	v05.00
Valid from:	31 July 2023
Review date:	1 January 2025
Expiry date:	31 July 2025

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). 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. Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.londonimms@nhs.net

[1] This includes any relevant amendments to legislation.

Change history

Version number	Change details	Date
V01.00	New PHE PGD	10 July 2015
V02.00	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® license • 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	4 May 2017
V03.00	MenACWY PGD amended to: • include additional healthcare practitioners in Section 3 • refer to vaccine incident guidelines in off-label and storage sections • remove the exclusion of individuals who are at increased risk of invasive meningococcal infection and redirect from the inclusion criteria to the MenACWY Risk Groups PGD where applicable • extend expiry date through to the end of the school year (end of July) • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs	20 February 2019
V04.00	MenACWY PGD amended to: • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs and updated references	14 June 2021
V05.00	MenACWY PGD amended to: • include particulars pertaining to an additional licensed MenACWY conjugate vaccine (MenQuadfi®) • include considerations for individuals previously immunised with MenACWY conjugate vaccine • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 • replace Public Health England and PHE with UKHSA, including branding and updated contact details • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs	16 June 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		16 June 2023
Doctor	Dr Shamez Ladhani Paediatric Infectious Diseases Consultant, UKHSA		16 June 2023
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisation and Vaccine Preventable Diseases Division, UKHSA		16 June 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
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSE
Rosie Furner	Pharmacist, Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead, Southbourne Surgery
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Lead Pharmacist, Medicines Governance, UKHSA
Elizabeth Luckett	Senior Screening & Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands
Mary Ramsay CBE	Director of Public Health Programmes, UKHSA
Tushar Shah	Lead Pharmacy Advisor, NHSE London

2. Organisational authorisations

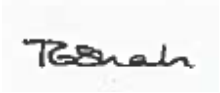
The PGD is not legally valid until it has had the relevant organisational authorisation.

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 – London authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
This PGD must only be used by specified registered healthcare professionals working for providers that are directly commissioned by NHS England - London, or who are administering vaccinations as part of a national immunisation programme, and who have been named and authorised to practice under it.
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Chief Nurse, NHS England - London	Jane Clegg		28/06/2023

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Director of Nursing Leadership and Quality, NHS England – London	Gwen Kennedy		29/06/2023
Lead Pharmacy Adviser, NHS England - London	Tushar Shah		28/06/2023

Local enquiries regarding the use of this PGD may be directed to england.londonimms@nhs.net

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 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 and 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 products 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 for Registered Healthcare Practitioners • 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 **Individual practitioners 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 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, detailed in the inclusion criteria, against *Neisseria meningitidis* serogroups A, C, W and Y in accordance with the recommendations given in Chapter 22 of Immunisation Against Infectious Disease: 'The Green Book' and Guidance for Public Health Management of Meningococcal Disease in the UK.
Criteria for inclusion	Individuals who are: • eligible for routine MenACWY immunisation, that is the 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, who have missed the routine vaccination offer in school years 9 or 10, who have missed the routine offer and have unknown or incomplete MenACWY vaccination status, until their 25th birthday. • aged 10 years until their 25th birthday with an incomplete or unknown MenC vaccination history • prospective students until their 25th birthday 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 2 weeks before attending university to ensure timely protection. • a close contact of a confirmed case of invasive meningococcal disease due to serogroups A, C, W or Y, **and who have not been vaccinated with MenACWY conjugate vaccine in the last 12 months** • in a cohort recommended to receive MenACWY immunisation following a local outbreak of invasive meningococcal disease and specific advice from UKHSA and the local Health Protection Team Note: Individuals with an underlying medical condition which puts them at increased risk from invasive meningococcal disease, such as individuals with asplenia, splenic dysfunction or complement disorders (including those on, or due to receive, complement inhibitor treatment such as eculizumab), may require additional routine vaccination outside the inclusion criteria for this PGD - see MenACWY Risk Groups PGD and Chapter 7 of the Green Book.
Criteria for exclusion[2] (continued over page)	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 previously received MenACWY conjugate vaccine from 10 years of age and are due to be called for their routine vaccination offer in line with the national programme, with the exception of contacts of confirmed invasive meningococcal disease due to serogroups A, C, W or Y • require vaccination for occupational health reasons, such as laboratory workers working with meningococci

[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.

Criteria for exclusion (continued)	• 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)
Cautions including any relevant action to be taken	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 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 from their tenth birthday do not routinely require further MenACWY immunisation, with the exception of contacts of confirmed invasive meningococcal disease due to group A, C, W or Y infection. Contacts of such confirmed cases should be offered the MenACWY conjugate vaccine if not received in the preceding 12 months. 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 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 individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in 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 individual's behalf, must be obtained for each administration. Advise 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	**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 syringes or **MenQuadfi®**, 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▼	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 page)	Administration by deep subcutaneous injection to individuals 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, as is MenQuadfi® for children under 12 months. Nimenrix® is licensed from 6 weeks of age for a schedule with a 2 month interval between doses, but a one month interval is in accordance with the advice in Chapter 22 of the Green Book. All vaccines are recommended in accordance with the advice in Chapter 22 of the Green Book. Where possible, administer a vaccine licensed for the age of the individual. If no licensed vaccine is available, then an alternative vaccine may be given off-label to avoid undue delay.

Off-label use (continued)	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 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 or 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	The MenACWY vaccines must be reconstituted in accordance with the manufacturer's instructions prior to administration. Following reconstitution, MenACWY conjugate vaccine should be given as a single 0.5ml dose by intramuscular (IM) 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 . 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 vaccine should be inspected for particles and discolouration before preparation and administration. Should either occur, discard the vial in accordance with local procedures. It is recommended that the vaccine be administered immediately after reconstitution, to minimise loss of potency. Discard reconstituted vaccine if it is not used within 8 hours (see Storage section). The SPCs for Menveo®, Nimenrix® and MenQuadfi® provide further guidance on reconstitution and administration and are available from the electronic Medicines Compendium.
Dose and frequency of administration	Note: Unless the individual is confirmed to have been immunised against the relevant meningococcal group within the preceding 12 months, vaccination should be offered to close contacts of any age **Aged 12 months and over** Single 0.5ml dose. **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 and administered	Single dose of 0.5ml per administration.
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. Vaccine for the national immunisation programme should not be used for the vaccination of contacts of confirmed cases and in outbreaks of MenACWY infection. Vaccine should be ordered from the manufacturers or their wholesalers. 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 the 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. 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 syringes, 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. MenACWY conjugate vaccine may be given at the same time as other vaccines. An interval of at least 8 weeks should be observed between Hib/MenC and MenACWY vaccination, to further boost immune response to the MenC component. A detailed list of interactions associated with MenACWY vaccines are provided in the respective SPCs, available from the electronic Medicines Compendium.

Identification and 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, irritability, fever and injection-site pain, erythema and induration and loss of appetite Gastrointestinal 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® is 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 Yellow Card reporting scheme, or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Reporting adverse reactions is particularly important for black triangle products, which are newer to market. 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 the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate. • Protect yourself against meningitis and septicaemia • Meningitis and septicaemia: information for new university entrants For parents of children under 12 months who are contacts of cases: • Why is my child being offered an 'off-label' vaccine. For resources in accessible formats and alternative languages, please visit https://www.healthpublications.gov.uk/
Patient advice and follow up treatment (continued over page)	Menveo®,Nimenrix® or MenQuadfi® will only confer protection against *Neisseria meningitidis* groups A, C, W and Y. The vaccine will not protect against any other *Neisseria meningitidis* serogroups. Individuals should continue to seek prompt medical attention at the first signs of possible meningitis infection. Inform the individual, parent or carer of possible side effects and their management. Give advice regarding normal reaction to the injection, for example redness and pain at the injection site.

Patient advice and follow up treatment (continued)	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 Yellow Card scheme. When applicable, advise the individual, parent or carer when the subsequent dose is due. When administration is postponed, advise the individual, parent or carer when to return for vaccination.
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. 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. 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. **Individuals previously vaccinated with MenACWY vaccine** Individuals who have been previously vaccinated for travel purposes since their tenth birthday do not require a repeat dose under the routine MenACWY immunisation programme, unless they are identified as a close contact of a confirmed case of invasive meningococcal disease due to serogroups A, C, W or Y. Conversely, if an individual was previously vaccinated with MenACWY vaccine under 10 years of age, an additional dose should be offered as part of the national adolescent MenACWY immunisation programme. If not vaccinated in the previous 12 months, irrespective of their age, all identified close contacts of a confirmed case of invasive meningococcal disease should be offered MenACWY conjugate vaccine. Meningococcal polysaccharide vaccines are discontinued and no longer licensed in the UK. Previous vaccination with meningococcal polysaccharide vaccines should not be counted as a valid dose when taking a history from the individual, their parent or carer.
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 the immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of the vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if the individual is excluded or declines immunisation • details of any adverse drug reactions and actions taken • the vaccine was supplied via PGD Records should be signed and dated (or password-controlled on e-records).

Records (continued)	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 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 30 May 2022 http://www.medicines.org.uk/emc/medicine/26514 • Menveo® Summary of Product Characteristics. GlaxoSmithKline UK, updated 30 December 2022 http://www.medicines.org.uk/emc/medicine/27347 • MenQuadfi® Summary of Product Characteristics. Sanofi Pasteur, updated 11 March 2022 https://www.medicines.org.uk/emc/product/12818/ • Immunisation Against Infectious Disease: The Green Book, Chapter 22, updated 17 May 2022 https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22 • Guidance for Public Health Management of Meningococcal Disease in the UK. Published 13 March 2018, updated 06 August 2019 https://www.gov.uk/government/publications/meningococcal-disease-guidance-on-public-health-management • Meningococcal ACWY (MenACWY) vaccination programme https://www.gov.uk/government/collections/meningococcal-acwy-menacwy-vaccination-programme • Meningococcal Disease: Guidance, Data and Analysis. Last updated 29 March 2023 https://www.gov.uk/government/collections/meningococcal-disease-guidance-data-and-analysis **General** • NHSE Health Technical Memorandum 07-01: Safe 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 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. Updated 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 7 July 2022 https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet
MenACWY PGD v05.00 Valid from: 31 July 2023 Expiry: 31 July 2025

Before signing this 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 [the following named organisation ……. for the above named healthcare 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.