NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Administration Of Haemophilus Influenzae Type B And Meningococcal C Conjugate Vaccine (Hib/MenC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from Public Health Scotland Administration Of Haemophilus Influenzae Type B And Meningococcal C Conjugate Vaccine (Hib/MenC) Patient Group Direction (PGD) Template, Version 3.0 – PHS Publication date 1st June 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/HibMenC/1505	**Review Date:** 31st May 2026 **Expiry Date:** 31st May 2026	**Date Approved by NoS:** 12th November 2024

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 3.0

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/HibMenC/MGPG1215, Version 2.1.1

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
2.0	1st June 2022 (PHS Version Unpublished by NoS)		
3.0	21st May 2024	Reference to NoS Appendix 1 and 2.	Authorisation
		Training requirements for NoS.	Continuing education and training

PHS recent changes

Version	Date	Summary of changes
3.0	1st June 2024	The following changes to version 2.0 of the PGD have been made: • Minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs. • Observation following vaccination section updated to include advice on driving post-immunisation. • Inclusion criteria, Frequency and is the use out with the SmPC sections updated to remove reference to the Scottish Haematology Society vaccination policy (Post HSC Transplantation).

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Contents

Authorisation

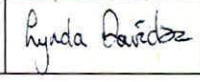
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Daniel Chandler	Signature		Date Signed	27/09/2024
Pharmacist	Kirsten Smith	Signature		Date Signed	29/10/2024
Nurse	Lynda Davidson	Signature		Date Signed	03/10/2024

Approved for use within NoS by:

NoS Group Chair	Signature	Date Signed
Lesley Coyle		01/11/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		12/11/2024

Version 3.0 – Approved for NoS from 12th November 2024

1. Clinical situation

1.1. Indication

Immunisation of individuals, against Haemophilus influenzae type b (Hib) and meningococcal group C disease (MenC).

1.2. Inclusion criteria

- Individuals aged from their first birthday to under 10 years of age and require a booster or primary dose of MenC and Hib.
- Individuals aged from their first birthday to under 10 years of age and are unimmunised or incompletely immunised against Hib or MenC.
- Individuals requiring vaccination for the prevention of secondary cases of Meningococcal C, following specific advice from NHS Board Health Protection Team.
- Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- Are less than 1 year of age, unless indicated for the prevention of secondary cases of MenC disease.
- Have had a confirmed anaphylactic reaction to a previous dose of Hib or MenC containing vaccine or to any components of the vaccine, including any conjugate vaccines where tetanus toxoid is used in the conjugate.
- Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex-free.
- Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).

1.4. Cautions/need for further advice/circumstances when further advice should be sought from a doctor

The Green Book advises that there are very few individuals who cannot receive Hib/MenC vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

If a seizure associated with a fever occurred within 72 hours of a previous immunisation, immunisation should continue as recommended if a cause is identified or the child recovers within 24 hours. However, if no underlying cause has been found and the child did not recover completely within 24 hours, further immunisation should be deferred until the condition is stable (as assessed by an appropriate clinician such as their GP or paediatrician).

The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations.

However, re-immunisation may need to be considered. Seek medical advice as appropriate.

Co-administration with other vaccines

Hib/MenC vaccine can be given at the same time as other vaccines.

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.

Syncope

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.

Pregnancy and breastfeeding

Meningococcal and Hib-containing 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 bacterial vaccines.

1.5. Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

If aged less than 1 year, Hib/MenC is not routinely indicated unless indicated for the prevention of secondary cases of MenC disease.

If aged 10 years and over or has received a dose of Hib and MenC conjugate containing vaccine from 1 year of age, Hib/MenC immunisation is not routinely indicated.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

1.6. Action if patient declines

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

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

Haemophilus influenzae type b and meningococcal group C conjugate (Hib/MenC) vaccine.

Haemophilus influenzae type b and meningococcal group C conjugate vaccine (conjugated to tetanus toxoid as carrier protein):

Menitorix® - Powder and solvent for solution for injection.

2.2. Route of administration

Administer by intramuscular injection. The deltoid region of the upper arm may be used in individuals over one year of age. The anterolateral aspect of the thigh should be used for infants under one year vaccinated for the prevention of secondary cases of MenC disease.

For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see the 'Green Book' Chapter 4).

The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration.

The vaccine's normal appearance is a white powder and a clear colourless solvent. Following reconstitution, the vaccine is a clear colourless solution.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

2.3. Dosage

0.5mL

2.4. Frequency

Routine Childhood Immunisation Schedule

A single dose to be administered, usually on or after their first birthday, although it may be administered until 10 years of age.

When primary vaccination with Hib has been delayed, the Hib booster dose (Hib/MenC) may be given at the scheduled visit, on or after their first birthday, provided it is at least 4 weeks since the last primary Hib dose was administered.

Incomplete immunisation history

Children from their first birthday to under 10 years of age who have completed a primary course of diphtheria, tetanus, pertussis and polio but have not received Hib containing vaccines should receive a single dose of Hib/MenC vaccine.

All unimmunised or incompletely immunised children under 10 years of age require one dose of Hib and MenC over the age of 1 year in accordance with the vaccination of individuals with uncertain or incomplete immunisation status flow chart.

Prevention of secondary cases of Meningococcal C disease

Vaccination for the prevention of secondary cases of Meningococcal C disease should be in accordance with recommendations from the local Public Health Protection Team and informed by the Public Health England Guidance for Public Health Management of Meningococcal Disease in the UK.

2.5. Duration of treatment

See frequency section.

2.6. Maximum or minimum treatment period

See frequency section.

2.7. Quantity to supply/administer

See frequency section.

2.8. ▼ black triangle medicines

No

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use out with the SmPC?

Yes

Administration of Hib/MenC vaccine to individuals aged 2 years and over is off-label but is indicated under this PGD in accordance with recommendations for the vaccination of individuals with uncertain or incomplete immunisation status, relevant chapters of the 'Green Book'.

The Hib/MenC vaccine SmPC states, "Menitorix® should be used in accordance with official recommendations". The use of Hib/MenC vaccine to provide a single priming dose of MenC to individuals from their first birthday is not covered by the SmPC but is in accordance with advice from JCVI (see MenC vaccination schedule planned changes from July 2016).

The Hib/MenC vaccine SmPC also states, "The timing of the booster dose should be from the age of 12 months onwards and at least 6 months after the last priming dose." However, when primary vaccination has been delayed, the Hib booster dose may be given at the scheduled visit provided it is at least 1 month since the last primary dose was administered in accordance with recommendations for the vaccination of individuals with uncertain or incomplete immunisation status.

Administration of Hib/MenC vaccine by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Green Book, Chapter 4 and Chapter 22.

Administration of Hib/MenC for the prevention of secondary cases of MenC disease is not covered by the Menitorix® SmPC, but Hib/MenC vaccine may be given as an alternative to MenACWY in accordance with PHE Guidance for Public Health Management of Meningococcal Disease in the UK.

Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines or National Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.

2.11. Storage requirements

Vaccine should be stored at a temperature of +2° to +8°C.

Store in the original packaging to protect from light.

Do not freeze.

After reconstitution, the vaccine should be administered promptly or kept in the refrigerator (2°C – 8°C). If it is not used within 24 hours, do not administer the vaccine. Experimental data show that the reconstituted vaccine could also be kept up to 24 hours at ambient temperature (25°C). If it is not used within 24 hours, do not administer the vaccine.

NHS Board guidance on Storage and Handling of vaccines should be observed.

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 National Vaccine Incident Guidance.

2.12. Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

Local reactions following vaccination are very common such as pain, swelling, or redness at the injection site. A small painless nodule may form at the injection site.

Mild side effects such as irritability, loss of appetite, drowsiness and slightly raised temperature commonly occur. Less commonly crying, diarrhoea, vomiting, atopic dermatitis, rash, malaise and fever over 39.5˚C have been reported.

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of severe adverse reaction, individuals should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://www.mhra.gov.uk/yellowcard

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individual:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Supply immunisation promotional material as appropriate.

Individual advice / follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://www.mhra.gov.uk/yellowcard
- Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection.
- When administration is postponed advise the individual how future vaccination may be accessed.
- When applicable, advise individual/parent/carer when the subsequent dose is due.

3.4. Observation following vaccination

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination. Following immunisation, patients remain under observation in line with NHS board policy.

3.5. Follow up

Not applicable.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)
- pharmacists currently registered with the General Pharmaceutical Council (GPhC)
- chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)
- dental hygienists and dental therapists registered with the General Dental Council
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it
- must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions
- must have access to the PGD and associated online resources
- should fulfil any additional requirements defined by local policy.

Employer

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

- Have undertaken NoS PGD module training on TURAS Learn
- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
- Have undertaken immunisation training where available
- Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

- Immunisation against Infectious Disease [Green Book].
- Immunisation against Infectious Disease [Green Book] chapter 16.
- Immunisation against Infectious Disease [Green Book] chapter 22.
- Guidance for Public Health Management of Meningococcal Disease in the UK.
- Vaccination of individuals with uncertain or incomplete immunisation status.
- Current edition of British National Formulary.
- Marketing authorisation holder's Summary of Product Characteristics.
- All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).
- Professional Guidance on the Administration of Medicines in Healthcare Settings 2019.
- Professional Guidance on the Safe and Secure Handling of Medicines.

7. PHS Version History

Version	Date	Summary of changes
1.0	1 September 2021	Version 1.0 new PGD
2.0	1 June 2022	• Inclusion criteria expanded to include other patient groups outwith the Scottish childhood immunisation programme. • Frequency section updated to include dosing information for the other patient groups outwith the Scottish childhood immunisation programme. • Use out with SmPC section has been updated to include the off label use of the vaccine for secondary cases of meningococcal C disease and revaccination following haemopoietic stem cell transplant.
3.0	1 June 2024	The following changes to version 2.0 of the PGD have been made: • Minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs. • Observation following vaccination section updated to include advice on driving post-immunisation. • Inclusion criteria, Frequency and is the use out with the SmPC sections updated to remove reference to the Scottish Haematology Society vaccination policy (Post HSC Transplantation). •

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NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1 - Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Haemophilus Influenzae Type B And Meningococcal C Conjugate Vaccine (Hib/MenC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 3.0

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Administration Of Haemophilus Influenzae Type B And Meningococcal C Conjugate Vaccine (Hib/MenC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 3.0
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**