Medicine Protocol for the Administration of Nimenrix vaccine (MenACWY) by registered nurses and registered midwives

This medicine protocol is a specific written instruction for the administration of Nimenrix (MenACWY) Vaccine to students in Second Level School by registered nurses and registered midwives. This medicine protocol is valid for the 2019/2020 HSE School Immunisation Programme.

This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer Nimenrix vaccine (MenACWY) with reference to and guidance from Nursing & Midwifery Board of Ireland, National Immunisation Advisory Committee, National Immunisation Office, HSE and in accordance with the Summary of Product Characteristics for Nimenrix vaccine (MenACWY) as detailed by the Health Products Regulatory Authority at www.hpра.ie:

- Health Services Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive
- National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians of Ireland National Immunisation Advisory Committee (Online Update available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/)
- Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/Scope-of-Practice/Nursing-Practise-Scope-Definition

The Nursing and Midwifery Board of Ireland defines medicine protocols as "written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect" (An Bord Altranais, 2007).
**Medicine Protocol for the Administration of Nimenrix Vaccine (MenACWY) by registered nurses and midwives to students in Second Level School through a School Immunisation Programme**

|-----------------------------|--------------------------------|

## 1.0 Critical Elements

| Name of Organisation where protocol applies | Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE). This Medicine Protocol applies to:  
  • Registered nurses and midwives involved in the supply and administration of the Nimenrix (MenACWY) vaccine to students in second level school through a School Immunisation Programme. |
| Date the protocol comes into effect | September 2019 |
| Date for review of protocol | May 2020 |
| Document prepared by: | Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the National Immunisation Office (NIO) at the request of Dr Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE |
| Names and Signatures of the employing authority who is authorising the implementation of the protocol | **“On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation”**  
  Name: Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE  
  Signature: [Signature]  
  Name: Dr Colm Henry, Chief Clinical Officer, HSE  
  Signature: [Signature]  
  Name: Ms Mary Wynne, Nursing and Midwifery Services Director, HSE  
  Signature: [Signature] |

Medicine Protocol for the Administration of Nimenrix Vaccine (MenACWY) 2019
### 2.0 Clinical Criteria

<table>
<thead>
<tr>
<th>Clinical Condition for use of the protocol</th>
<th>The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of Meningococcal Group ACWY (MenACWY) disease.</th>
</tr>
</thead>
</table>
| Circumstances in which the medicine protocol applies | The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE)  

The Nimenrix (MenACWY) vaccine is given as a vaccination for first year students in second level schools (or age equivalent)  

https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/  

For 2019/2020 MenACWY may also be given, to students who are outside the First year cohort group, but are still in school, who missed the Men C vaccine in first year due to medical reasons/exceptional circumstances and whose parents/legal guardians now request MenACWY vaccine.  

*MenACWY vaccine should only be offered to students who commenced in 1st year since 2019/2020*

| Inclusion criteria for students treatment using the medicine protocol | Students in 1st year of second level school and age equivalent in special schools and home schooled students  

See https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf  

For 2019/2020 MenACWY may also be given, to students who are outside the First year cohort group but are still in school, who missed the Men C vaccine in first year due to medical reasons/exceptional circumstances and whose parents/legal guardians now request MenACWY vaccine  

Students with valid consent.  

If Men C vaccine has recently been received, defer Men ACWY vaccine until at least 2 months after Men C vaccine. |
| Exclusion criteria for students when using the medicine protocol | A known history of anaphylactic or hypersensitivity reaction to Nimenrix vaccine or any of its components including Sucrose and Trometamol  

Already received a dose of conjugated Men ACWY vaccine at the age of 10 years or older.  

Acute febrile illness: The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation.  

Students with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia). |
### Actions to be taken for those who are excluded from the Protocol

<table>
<thead>
<tr>
<th>Actions</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>• All students meeting exclusion criteria must be referred to the medical practitioner for an individual assessment, except where excluded due to receipt of Men ACWY vaccine at 10 years or older who therefore do not require further vaccination.</td>
<td></td>
</tr>
<tr>
<td>• Document action in clinical notes</td>
<td></td>
</tr>
<tr>
<td>• Where Nimenrix Vaccine (MenACWY) is prescribed following medical assessment, the nurse or midwife may administer Nimenrix Vaccine (MenACWY) within their scope of practice.</td>
<td></td>
</tr>
<tr>
<td><strong>Note:</strong> <strong>In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Description of circumstances and referral arrangements when further advice or consultation is required

Refer the student to the Medical Practitioner in the event of:

- Adverse reaction
- Other clinical concerns

### Documentation required to support implementation of the medicine protocol

A consent form must be completed by the parent/legal guardian for all students who receive the vaccine. Appropriate details including the batch number must be recorded on the consent form.

The following documents will be available at each school vaccination session:

- Vaccination session forms
- Blank Vaccine consent forms
- Patient held record cards
- Health Products Regulatory Authority Adverse Reaction Reporting forms
- HSE Incident/near miss report forms (NIRF, 2018)
- Tear pads post vaccination
- It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Menjugate vaccine which includes the following:
  - Information for Staff: School Immunisation programme 2019/2020
  - Medicine Protocol for the administration of Nimenrix vaccine (MenACWY) vaccine Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating Medication Protocol for the Administration of Epinephrine (adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (HSE 2019), [https://www.hse.ie/eng/health/immunisation/hcinfo/fluinfo/adrenalineprotocol.pdf](https://www.hse.ie/eng/health/immunisation/hcinfo/fluinfo/adrenalineprotocol.pdf)

### 3.0 Name of Medicine

**Link to Medicine**

Nimenrix Vaccine (MenACWY)

**Details of product information and other data including instructions for supply and administration**

**Link to Summary of Product Characteristics and Patient Information Leaflet:**

is available from the Health Products Regulatory Authority at [www.hpra.ie](http://www.hpra.ie)

| Procedure for reporting and documentation of errors and near misses involving the medication | In the case of medicine errors that directly involve the student, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the student and closely monitor them for any adverse reactions.

Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and medical practitioner.

The incident must be reported to the relevant line manager as soon as possible.

The incident and all actions taken must be promptly recorded in the student's documentation/notes and the relevant report form completed.

The incident and all sections taken must be promptly recorded and the relevant National incident Management Report Form completed (National incident Management Report Form (NIRF-01-V10)) (May 2018):

The student’s parent and/or legal guardian must be informed of the incident.

An incident report form must be completed by the registered nurse or registered midwife and forwarded to the relevant line manager as per local policy.

Any suspected adverse reactions associated with medication errors must be reported to the HPRA as outlined below.

Any errors and near misses not involving medication, the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report form and forwarded to the relevant line manager as per local policy.

| Resources and equipment required | • Vaccine
• Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2°C to +8°C
• Disposable kidney dishes/coloured trays
• Gauze swabs/Plasters |

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**Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)**

The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out in line at [https://www.hpra.ie](http://www.hpra.ie) or through use of the yellow card system which is available in the downloadable format from the HPRA website, or on request from the HPRA.

The incident and all actions taken must be promptly recorded in accordance with the criteria outlined by the HPRA: *Management of a Patient with Anaphylaxis: Treatment in the Community* (National Immunisation Advisory Committee, 2019) – available online at

[https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf)
| Audit process to identify appropriate use of the protocol or unexpected outcomes | All documentation will be held for review and audit purposes as per local policy. |

### 4.0 Information for student/parent/guardian

<table>
<thead>
<tr>
<th>Advice to be given to the student/parent/legal guardian before treatment</th>
<th>HSE 1st year vaccination programme information leaflet must have been supplied with the Consent form to each student/parent/legal guardian prior to administration of the vaccine.</th>
</tr>
</thead>
<tbody>
<tr>
<td>After Treatment</td>
<td>An Information Tear Pad, stating date and time of vaccination must be given to all students for parental/guardian’s attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccination.</td>
</tr>
<tr>
<td></td>
<td>The student must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the registered nurse or registered midwife.</td>
</tr>
<tr>
<td>Details of any necessary follow-up, action and referral arrangements</td>
<td>In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.</td>
</tr>
</tbody>
</table>

### 5.0 Staff authorised to use this medicine protocol
<table>
<thead>
<tr>
<th>Professional qualifications, training, experience and competence required prior to working under this medicine protocol</th>
<th>Registered nurse or registered midwife, maintained on the live register of The Nursing and Midwifery Board of Ireland.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professional Qualifications:</strong></td>
<td>Education programme for nurses and midwives on the use of <em>Medicine Protocol for the Administration of Meningococcal ACWY Vaccine (MenACWY)</em> through a School Immunisation Programme.</td>
</tr>
<tr>
<td>Training, Experience, Competence:</td>
<td>- Basic Life Support for Health Care Workers within 2 years.</td>
</tr>
<tr>
<td></td>
<td>- &quot;National Anaphylaxis Education Programme for Health Care Professionals&quot;, initially attends a classroom based programme. Updates available on <a href="http://www.hseland.ie">www.hseland.ie</a> &quot;National Anaphylaxis Education Programme for Health Care Professionals&quot; within 2 years.</td>
</tr>
<tr>
<td></td>
<td>- Injection technique education programme. (Local CNME/CNE)</td>
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<tr>
<td></td>
<td>- &quot;Hand Hygiene for HSE Clinical Staff&quot; <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
<tr>
<td></td>
<td>- &quot;Aseptic Non Touch Technique&quot; (ANTT) <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
<tr>
<td></td>
<td>- &quot;Immunisation Foundation Programme&quot; <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
<tr>
<td></td>
<td>- GDPR Guidelines <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
</tbody>
</table>
References

Health Products Regulatory Authority available at [www.hpra.ie](http://www.hpra.ie) (accessed 27th June 2019)

Health Service Executive (2019) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or suspected anaphylaxis incorporating Medicine protocol for the Administration of Epinephrine (Adrenaline) injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis*. Dublin: Health Service Executive.


Nimenrix Vaccine (MenACWY) Pfizer *Summary of Product Characteristics and Patient Information Leaflet*, Available at [www.hpra.ie](http://www.hpra.ie)


Irish Medicines Board *(Miscellaneous Provision) Act 2006 (No. 3 of 2006) (Section 10(1(ii))).* Dublin: Stationery Office


Medicine Protocol for the Administration of Nimenrix Vaccine (MenACWY), 2019
29 July 2011

Mr. Michael Shannon
Assistant National Director,
Clinical Strategy and Programme Directorate, Health Service Executive
Dr. Steeven's Hospital
Dublin 8

Dear Mr. Shannon,

Thank you for informing An Bord Altranais of the current work undertaken by the Office of the Nursing and Midwifery Services Director in relation to the national programme for the administration of the immunisations by nurses and midwives as part of the school immunisation programmes provided by the Health Service Executive. I note your request for professional guidance from An Bord Altranais regarding the scope of practice of nurses and midwives administering vaccines under medication protocol.

An Bord Altranais has published detailed guidance for developing medication protocols and general information about the professions' role in vaccinations in Guidance to Nurses and Midwives on Medication Management (2007) and the e-learning programme Guide to Medication Management (An Bord Altranais and the National Council, 2007).

The Nursing Board recognises and supports the role of the registered nurse and midwife in utilising the medication protocol for the administration of immunisations to children as part of the school immunisation programme. We note the key supports for registrants' scope of practice in implementing these medication protocol have been incorporated in the individual content of the medication protocols in association with reference to the education and clinical supports as you have outlined in your letter.

An Bord Altranais recognise that the HSE medication protocols complement the guidance of the Nursing Board and facilitate the achievement and maintenance of professional competency and outline the accountability of the nurse midwife asked to participate with this medication protocol.

I hope this information is of assistance to you.

Yours sincerely,

Dr. Mark O'Reilly
Chief Executive Officer

Office of Nursing Services Director
- 3 AUG 2011

RECEIVED

Nimenrix vaccine, IPV Infantis vaccine, Pneumovax M-MRV AXP PRO vaccine and Bovirrix vaccine

Medicine Protocol for the Administration of Nimenrix Vaccine (MenACWY), 2019