Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis, and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content) by registered nurses and registered midwives

This medicine protocol is a specific written instruction for the administration of IPV Boostrix Vaccine Tdap/IPV (diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content), to children in Primary 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 IPV Boostrix (diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)), with reference to and guidance from Nursing & Midwifery Board of Ireland, National Immunisation Group, National Immunisation Office, HSE and in accordance with the Summary of Product Characteristics for IPV Boostrix vaccine as detailed by the Health Products Regulatory Authority at www.hpra.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 for nurses and midwives for the management of 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/)

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 medicine protocol is in effect” (An Bord Altranais, 2007).
**Medicine Protocol for the Administration of IPV Boostrix Vaccine by registered nurses and midwives to children/students in Primary Level School through a School Immunisation Programme**

<table>
<thead>
<tr>
<th>Document reference number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ONMSD-2018-007, ONMSD2019 009</td>
</tr>
</tbody>
</table>

### 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 IPV Boostrix vaccine to children/students in primary 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, National Director of Clinical Strategy and Programmes, HSE

**Signature:** [Signature]

**Name:** Ms Mary Wynne, Nursing and Midwifery Services Director, HSE

**Signature:** [Signature]
### 2.0 Clinical Criteria

| **Clinical Condition for use of the protocol** | The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio) disease. IPV Boostrix is given as a booster vaccination to children who have previously received DTaP/IPV containing vaccines in the primary childhood immunisation schedule. |
| **Circumstances in which the medicine protocol applies** | The School Immunisation Programme (SIP) will be delivered annually by the Health Service Executive (HSE). The aim of the immunisation programme is to provide a booster dose of diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine, vaccine to children who previously completed primary vaccination against these diseases as recommended in the Immunisation Guidelines for Ireland [https://www.hse/eng/health/immunisation/hcpinfo/guidelines/]. |
| **Inclusion criteria for children/students treatment using the medicine protocol** | All children in primary school usually delivered in junior infants and age equivalent in e.g. special schools and home schooled students. [https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf](https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf) Children with valid consent. |
| **Exclusion criteria for children/students using the medicine protocol** | Children who have not commenced or completed immunisation course. A known history of anaphylactic or hypersensitivity reaction to IPV Boostrix or any of the vaccine’s constituents including neomycin or polymyxin. 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. Children with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia. Children who are immunocompromised either due to disease or treatment. |
| **Actions to be taken for those who are excluded from the Protocol** | • All children meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment. • Document action in clinical notes • Where IPV Boostrix vaccine is prescribed following medical assessment, the nurse or midwife may administer IPV Boostrix vaccine within their scope of practice. |

**Note:** In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).

| **Description of** | Refer the student to the Medical Practitioner |

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Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis, and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content), 2019
<table>
<thead>
<tr>
<th>circumstances and referral arrangements when further advice or consultation is required</th>
<th>in the event of:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Adverse reaction</td>
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<tr>
<td></td>
<td>Other clinical concerns</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Documentation required to support implementation of the medicine protocol</th>
<th>A consent form must be completed by the parent/legal guardian for all children who receive the IPV Boostrix 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:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Vaccination session form</td>
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<tr>
<td></td>
<td>• Blank Vaccine consent forms</td>
</tr>
<tr>
<td></td>
<td>• Vaccine Information Leaflets</td>
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<tr>
<td></td>
<td>• Patient held record cards</td>
</tr>
<tr>
<td></td>
<td>• Health Products Regulatory Authority Adverse Reaction Reporting forms</td>
</tr>
<tr>
<td></td>
<td>• HSE Incident/near miss report forms (NRIF, 2018)</td>
</tr>
<tr>
<td></td>
<td>• Tear pads for after vaccination</td>
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</tbody>
</table>

It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of IPV Boostrix vaccine which includes the following:

- Information for Staff: School Immunisation Programme 2019/2020
- Medicine Protocol for the administration of IPV Boostrix
- 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), available at https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf

<table>
<thead>
<tr>
<th>3.0 Name of Medicine</th>
</tr>
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<tbody>
<tr>
<td><strong>IPV Boostrix 2019/2020</strong></td>
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</table>

<table>
<thead>
<tr>
<th>Link to Medicine Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority at <a href="http://www.hpra.ie">www.hpra.ie</a></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Link to Summary of Product Characteristics</strong></td>
</tr>
<tr>
<td><strong>Link to Patient Information Leaflet:</strong></td>
</tr>
<tr>
<td><a href="https://www.hpra.ie/img/uploaded/swedocuments/2177440.PA1077_101_001.30520b2e-7f6b-4bfc-8784-63a77e38b2ed.000001plipv.170109.pdf">https://www.hpra.ie/img/uploaded/swedocuments/2177440.PA1077_101_001.30520b2e-7f6b-4bfc-8784-63a77e38b2ed.000001plipv.170109.pdf</a></td>
</tr>
</tbody>
</table>

| Procedure for the reporting and documentation of errors and near misses involving the medicine | In the case of medicine errors that directly involve the child, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the child 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/ or 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 child’s documentation/notes and the relevant report form completed.

The incident and all actions must be promptly recorded and the National Incident Management Report Form completed (National Incident Report Form (NIRF 01-V10)) (May 2018) available at: https://www.hse.ie/eng/about/gavd/incident-management/nirf-01-v10-person1.pdf

The child’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 should be reported to the HPRA as outlined below. (As per local policy).

Any errors and near misses not involving medications, 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.

<table>
<thead>
<tr>
<th>Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)</th>
</tr>
</thead>
</table>

- 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 or through the use of the yellow card system which is available in the downloadable format from the HPRA website, or on the 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

<table>
<thead>
<tr>
<th>Resources and equipment required</th>
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</table>

- Vaccine (pre-filled syringe)
- Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°
- Disposable kidney dishes/coloured trays
- Gauze swabs/Plasters
- Sharps bins, and bags for disposal of other hazardous material
- Alcohol hand rinse
- Access to telephone
- Resuscitation equipment and drugs in accordance with the *Management of a Patient with Anaphylaxis or suspected anaphylaxis,* (National Immunisation Advisory Committee, 2019) available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf
- Access to medical support
- Safe storage areas for medicines and equipment
- Current medicine protocol for IPV Boostrix Vaccine.

<table>
<thead>
<tr>
<th>Audit process to identify</th>
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Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis, and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content), 2019
<table>
<thead>
<tr>
<th><strong>Appropriate use of the protocol or unexpected outcomes</strong></th>
<th>All documentation will be held for review and audit purposes as per local policy.</th>
</tr>
</thead>
</table>

### 4.0 Information for child/student/parent/guardian

<table>
<thead>
<tr>
<th><strong>Advice to be given to the child/student/parent/guardian before treatment</strong></th>
<th>The HSE 4in1 and MMR vaccine Information for parents of children in Junior infant’s booklet must have been supplied with the consent form to each parent/legal guardian prior to administration of the Tdap/IPV vaccine.</th>
</tr>
</thead>
</table>
| **Advice to be given to the child/student/parent/guardian after treatment** | **After Treatment**
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.

The child/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 who is present. |

<table>
<thead>
<tr>
<th><strong>Details of any necessary follow-up, action and referral arrangements</strong></th>
<th>In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.</th>
</tr>
</thead>
</table>

### 5.0 Staff authorised to use this medicine protocol

| **Professional qualifications, training, experience and competence required prior to working under this medicine protocol** | Registered nurse or registered midwife, on the live register of The Nursing and Midwifery Board of Ireland. Education programme for nurses and midwives on the use of *Medicine Protocol for the Administration of IPV Boostrix Vaccine (Diphtheria, Tetanus, Poliomyelitis)* through a School Immunisation Programme.
• Basic Life Support for Health Care Workers within 2 years.
• “National Anaphylaxis Education Programme for Health Care Professionals”, initially attends a classroom based programme. Updates available on [www.hseland.ie](http://www.hseland.ie) “National Anaphylaxis Education Programme for Health Care Professionals” within 2 years.
• Injection technique education programme. (Local CNME/CNE)
• “Hand Hygiene for HSE Clinical Staff” [www.hseland.ie](http://www.hseland.ie)
• “Aseptic Non Touch Technique” (ANTT) [www.hseland.ie](http://www.hseland.ie)
• “Guide to Medicines Management” [www.hseland.ie](http://www.hseland.ie)
• “Immunisation Foundation Programme” [www.hseland.ie](http://www.hseland.ie)
• GDPR Guidelines [www.hseland.ie](http://www.hseland.ie) |
|---|---|

Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis, and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content), 2019
References


Health Products Regulatory Authority available at www.hpra.ie (accessed 31st January 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.


IPV Boostrix GlaxoSmithKline, Ireland Limited Summary of Product Characteristics and Patient Information Leaflet, text revised January 2019. Available at www.hpra.ie


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


National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians Ireland (Online Update available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/)


Nursing and Midwifery Board of Ireland (2015) Practice Standards for Midwives Dublin: Nursing and Midwifery Board of Ireland. And Midwifery Board of Ireland available at http://www.nmbi.ie/Standards-Guidance/Midwives-Standards

Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis, and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content), 2019

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
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.


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 Mairead Goldrick
Chief Executive Officer

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[1] Tetvax vaccine, IPV Infanrix vaccine, Priorix vaccine, M-M RVAXPRO vaccine and Boostrix vaccine