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 2018/2019 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:

- National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians of Ireland National Immunisation Advisory Committee (Online Update available at: http://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>
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<tr>
<th>Document number:</th>
<th>reference: ONMSD 2018-017</th>
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### 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 2018

**Date for review of protocol**: May 2019

**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 Image]

- **Name**: Dr Colm Henry, Chief Clinical Officer, HSE
- **Signature**: [Signature Image]

- **Name**: Ms Mary Wynne, Nursing and Midwifery Services Director, HSE
- **Signature**: [Signature Image]

Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis, and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content) Version 1, 2018
### 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 [http://www.hse/eng/health/immunisation/hcpinfo/guidelines/](http://www.hse/eng/health/immunisation/hcpinfo/guidelines/). |
| Inclusion criteria for children/students treatment using the medicine protocol | All children in junior infants of primary school and age equivalent in e.g. special schools and home schooled students. [http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf](http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/4in1mmr/schoolguidelines.pdf) |
| 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 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 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:

- Vaccination session form
- Blank Vaccine consent forms
- Vaccine Information Leaflets
- Patient held record cards
- Health Products Regulatory Authority Adverse Reaction Reporting forms
- HSE Incident/near miss report forms (NRIF, 2017)
- Tear pads for after vaccination

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:

- Guidelines for Staff: School Immunisation Programme 2018/2019
- Medicine Protocol for the administration of IPV Boostrix (diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine, by registered nurses and registered midwives to children in primary/second level school or age equivalent in special schools or home schooled children/students through the School Immunisation Programme.


### 3.0 Name of Medicine

<table>
<thead>
<tr>
<th>Link to Medicine</th>
<th>IPV Vaccine (Boostrix) 2018/2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.hp%D1%80%D0%B0.ie">www.hpра.ie</a></td>
<td></td>
</tr>
<tr>
<td>Link to Patient Information Leaflet:</td>
<td><a href="https://www.hp%D1%80%D0%B0.ie/img/uploaded/vaccines/PIL_PA1077101001.pdf">https://www.hpра.ie/img/uploaded/vaccines/PIL_PA1077101001.pdf</a></td>
</tr>
</tbody>
</table>
### Procedure for the management, reporting and documentation of errors and near misses involving the medication

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 child 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 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-V09)) (Jan 2017) available at [https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v09-person](https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v09-person)

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.

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

All adverse drug reactions or suspected adverse drug reactions following administration of the vaccine must be reported as soon as possible in accordance with criteria outlined by the Health Products Regulatory Authority (HPRA).

Reporting of suspected adverse reactions may be carried out on line at [http://www.hpra.ie](http://www.hpra.ie) or through use of the yellow card system which is available in a downloadable format from the HPRA website, or on request from the HPRA.

In the case of Anaphylaxis the incident and all actions taken must be promptly recorded in accordance with the Management of a Patient with Anaphylaxis HSE (2018) – available online at [http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf](http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf)

### Resources and equipment required

- 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
### 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 child/student/parent/guardian

<table>
<thead>
<tr>
<th>Advice to be given to the child/student/parent/guardian before treatment</th>
<th>HSE IPV Boostrix information leaflet must have been supplied with the consent form to each parent/legal guardian prior to administration of the 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. |
| Details of any necessary follow-up, action and referral arrangements | In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3. |

### 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 through a School Immunisation Programme  
Basic Life Support for Health Care Workers within the last two years.  
Approved Anaphylaxis Treatment Training programme initially, with updates as required to maintain individual competence [www.hseLand.ie](http://www.hseLand.ie)  
Competency for Injection Technique  

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- Access to medical support
- Safe storage areas for medicines and equipment
- Current medicine protocol for IPV Boostrix Vaccine.
References


Health Products Regulatory Authority available at [www.hpra.ie](http://www.hpra.ie) (accessed 25th February 2018)


IPV Boostrix GlaxoSmithKline, Ireland Limited *Summary of Product Characteristics and Patient Information Leaflet,* updated February 2018 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.


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\(^1\) 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 Maura Finucane
Chief Executive Officer

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\(^1\) Tetravac vaccine, IPV Infanrix vaccine, Priorix vaccine, M-M RVAXPRO vaccine and Boostrix vaccine