Medicine Protocol for the Administration of Tdap vaccine (Boostrix) adsorbed, reduced antigen(s) content by registered nurses and registered midwives

This medicine protocol is a specific written instruction for the administration of Boostrix Vaccine (a low dose Tetanus, Diphtheria, and Pertussis (acellular) vaccine (adsorbed, reduced antigen(s) content) (Tdap) 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 Tdap vaccine (Boostrix) 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 Tdap vaccine (Boostrix) 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 available at www.immunisation.ie
- 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) Practice Standards for Midwives. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/Midwives-Standards
- 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-Practice-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 Tdap Vaccine (Boostrix) by registered nurses and midwives to students in first year in Second Level School through a School Immunisation Programme**

<table>
<thead>
<tr>
<th>Document reference number:</th>
<th>ONMSD 2019 010 ONMSD to add</th>
</tr>
</thead>
</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 Boostrix vaccine to first year 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, 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 tetanus, diphtheria, and pertussis disease. Tdap (Boostrix) vaccine is given as a booster dose of tetanus, diphtheria, and pertussis vaccine to children in first year in second level school. For 2019/2020 Boostrix may also be given, to students who are outside the First year cohort group, but are still in school, who missed the Boostrix vaccine in first year due to medical reasons and whose parents/legal guardians now request Boostrix vaccine. |
| 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 offer a booster dose of the Tdap (diphtheria, tetanus and pertussis (acellular) vaccine Boostrix, to all first year students in second level schools and age equivalent in special schools and home schooled students) as recommended by NIAC in the Immunisation Guidelines for Ireland [https://www.hse.ie/eng/health/immunisation/hcinfo/guidelines/](https://www.hse.ie/eng/health/immunisation/hcinfo/guidelines/). For 2019/2020 Boostrix may also be given, to students who are outside the First year cohort group whose parents/legal guardians made contact with the vaccination team and requested that their unvaccinated child receives Boostrix vaccine and students in school outside first year (in 2019/2020) aged 16 years of age or older who request vaccination. |
| Inclusion criteria for student/service user treatment using the medicine protocol | Students in 1st year of second level school and age equivalent in 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) For whose parents/legal guardians made contact with the vaccination team and requested that their unvaccinated child receives Boostrix vaccine and students in school outside first year (in 2019/2020) aged 16 years of age or older who request vaccination. Students with valid consent. |
| Exclusion criteria for student/service treatment using the medicine protocol | A known history of anaphylactic or hypersensitivity reaction to Boostrix or to any of the Boostrix vaccine constituents. 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) Students who are immunocompromised either due to disease or treatment. |
| **Actions to be taken for those students who are excluded from the Protocol** | • All students meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment.  
• Document action in clinical notes  
• Where Tdap Vaccine (Boostrix) is prescribed following medical assessment, the nurse or midwife may administer Tdap Vaccine (Boostrix) 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 students who receive the 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 report adverse form  
• 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 for post vaccination  

It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Boostrix vaccine which includes the following:  
• Information for Staff: School Immunisation Programme 2019/2020  
• Medicine Protocol for the administration of Boostrix vaccine by registered nurses and registered midwives to students in first year in second level school and age equivalent in special schools and home schooled students through the School Immunisation Programme.  
• 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/guidelines/Anaphylaxis.pdf |
### 3.0 Name of Medicine

<table>
<thead>
<tr>
<th>Link to Medicine</th>
<th>Tdap Vaccine (Boostrix): 2019/2020</th>
</tr>
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<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><strong>Link to Summary of Product Characteristics:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Link to Patient Information Leaflet</strong></td>
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<tr>
<td><a href="https://www.hp%D1%80%D0%B0.ie/img/uploaded/swedocuments/2177440.PA1077_020_001.c3a82a06-8246-4f8b-899b-9f40420f17dd000001pl170109.pdf">https://www.hpра.ie/img/uploaded/swedocuments/2177440.PA1077_020_001.c3a82a06-8246-4f8b-899b-9f40420f17dd000001pl170109.pdf</a></td>
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</table>

### Procedure for the 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/or medical practitioner.

The incident must be reported to the relevant line manager as soon as possible. The incident and all sections taken must be properly recorded and the relevant National Incident Management report Form completed (National Incident Report Form (NIRF-01-V10)) [May 2018]: [https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v10-person1.pdf](https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v10-person1.pdf).

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

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

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

Any suspected adverse reactions associated with medication errors should 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 form and forwarded to the relevant line manager as per local policy.

### 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.hpра.ie](http://www.hpра.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
<table>
<thead>
<tr>
<th>Resources and equipment required</th>
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</thead>
<tbody>
<tr>
<td>- Vaccine (pre-filled syringe)</td>
</tr>
<tr>
<td>- Fridge/Cooler box with minimum/maximum thermometer to maintain cold chain temperature between +2° to +8°C</td>
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<tr>
<td>- Disposable kidney dishes/coloured trays</td>
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<tr>
<td>- Gauze swabs/Plasters</td>
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<tr>
<td>- Sharps bins and bags for disposal of other hazardous material</td>
</tr>
<tr>
<td>- Alcohol hand rinse</td>
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<tr>
<td>- Access to telephone</td>
</tr>
<tr>
<td>- Access to medical support</td>
</tr>
<tr>
<td>- Safe storage areas for medicines and equipment</td>
</tr>
<tr>
<td>- Current medicine protocol for Boostrix (Tdap) Vaccine.</td>
</tr>
</tbody>
</table>

4.0 Information for the student/parent/guardian

**Advice to be given to the student/parent/guardian before treatment**

HSE 1st year vaccination programme information booklet must have been supplied with the consent form to each student’s parent or legal guardian prior to administration of the vaccine.

**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 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.

**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,** Registered nurse or registered midwife, maintained on the live register of The Nursing
<table>
<thead>
<tr>
<th>Training, Experience, Competence:</th>
<th>and Midwifery Board of Ireland.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional Qualifications:</td>
<td>Education programme for nurses and midwives on the use of <em>Medicine Protocol for the Administration of Tdap vaccine (Boostrix) through a School Immunisation Programme</em>.</td>
</tr>
<tr>
<td></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.hsland.ie">www.hsland.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.hsland.ie">www.hsland.ie</a></td>
</tr>
<tr>
<td></td>
<td>• &quot;Aseptic Non Touch Technique&quot; (ANTT) <a href="http://www.hsland.ie">www.hsland.ie</a></td>
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<td></td>
<td>• &quot;Guide to Medicines Management&quot; <a href="http://www.hsland.ie">www.hsland.ie</a></td>
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<tr>
<td></td>
<td>• &quot;Immunisation Foundation Programme&quot; <a href="http://www.hsland.ie">www.hsland.ie</a></td>
</tr>
<tr>
<td></td>
<td>• GDPR Guidelines <a href="http://www.hsland.ie">www.hsland.ie</a></td>
</tr>
</tbody>
</table>
References


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


Tdap Vaccine (Boostrix) GlaxoSmithKline, Ireland Limited *Summary of Product Characteristics and Patient Information Leaflet*, SmPC revised January 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


Medicine Protocol for the Administration of Tdap (Boostrix) (adsorbed, reduced antigen(s) content), 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. Maire ó Muirchaoráin
Chief Executive Officer

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1 TetraVac vaccine, IPV Infanrix vaccine, Priorix vaccine, M-M RVAXPRO vaccine and Boostrix vaccine