Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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 2020/2021 HSE School Immunisation Programme.**

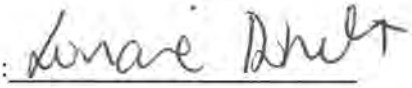
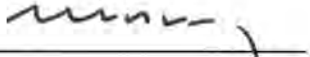
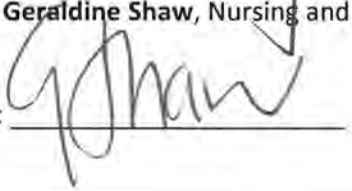
This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer Tdap vaccine (Boostrix) with reference to and guidance from Nursing & Midwifery Board of Ireland, National Nursing and Midwifery Working Group, 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 :

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais
- 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 Office) 2020 Supporting Information for Staff: Schools Immunisation Programme 2020/2021 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 (2014) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/Code.
- 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) *Recording Clinical Practice. Guidance to Nurses and Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Recording-Clinical-Practice
- 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 Tdap Vaccine (Boostrix) by registered nurses and midwives to students in first year in Second Level School through a School Immunisation Programme

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

Document reference number:	ONMSD 2020 - 010
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 2020
Date for review of protocol	May 2021
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 Lorraine Doherty, National Clinical Director Health Protection.
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. Lorraine Doherty**, National Clinical Director Health Protection, HSE Signature:  Name: **Dr Colm Henry**, Chief Clinical Officer, HSE Signature:  Name: **Dr Geraldine Shaw**, Nursing and Midwifery Services Director, HSE 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 2020/2021 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/eng/health/immunisation/hcpinfo/guidelines/. For 2020/2021 Boostrix may also be given, to students who are outside the First year cohort group who missed the Boostrix vaccine programme in first year due to exceptional/ medical reasons and whose parents/legal guardians now request it, or who were unable to attend the 2020 summer vaccine catch-up clinics.
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 For 2020/2021 Boostrix may also be given, to students who are outside the First year cohort group who missed the Boostrix vaccine programme in first year due to exceptional/ medical reasons and whose parents/legal guardians now request it, or who were unable to attend the 2020 summer vaccine catch-up clinics. 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	Discuss the student with the Medical Practitioner or lead nurse in the event of: • Previous adverse reaction • Other clinical concerns
Documentation required for the implementation of this 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 required at each school vaccination session: • Vaccination session report form • Blank vaccine consent forms • Patient held record cards • Health Products Regulatory Authority Adverse Reaction Reporting forms • HSE Incident/near miss report forms (NIRF, 2020) • 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: • Supporting Information for Staff: School Immunisation Programme 2020/2021 • 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	Tdap Vaccine (Boostrix): 2020/2021 **Dose** 0.5ml **Route** IM **Site** Deltoid (right side recommended)
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 www.hpra.ie**	**Link to Summary of Product Characteristics:** **https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1077-020-001_06062019113754.pdf** **Link to Patient Information Leaflet** **https://www.hpra.ie/img/uploaded/swedocuments/2177440.PA1077_020_001.c3a82a06-8246-4f8b-899b-9f40420f17dd.000001pl.170109.pdf**

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 Report Form (NIRF--01-V 11 March 2020): https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.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 (i.e. needle stick injury), 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. Refer 'EMI Tool Kit' (https://www.hpsc.ie/a-z/EMIToolkit/).
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 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
Resources and equipment required	• Vaccine (pre-filled syringe) • Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C) • 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 (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 Boostrix (Tdap) Vaccine.
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.
Advice to be given to the 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 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, training, and competence required prior to using this medicine protocol **Professional Qualifications** **Training and Competence:**	Registered nurse or registered midwife on the active register maintained by The Nursing and Midwifery Board of Ireland. National Schools Immunisation programme for registered nurses and registered midwives on the use of this medicine protocol. Basic Life Support for Health Care Providers within the last two years. Initial anaphylaxis programme *("National Anaphylaxis Education Programme for Health Care Professionals")* via HSELanD followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSELanD Anaphylaxis e-learning programme available at www.hse.ie. The registered nurse/midwife must complete the *"Competency Self - Assessment Tool for registered nurses and registered midwives to supply and administer vaccines under medicine protocols through a schools immunisation programme".* **Recommended:** E-*learning Guide to Medicine Management,* available at www.hseland.ie

	Introduction to Immunisation, available at www.hseland.ie

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Misuse of Drugs (Amendment) Regulations 2017, Statutory Instruments No.173 of 2017. Dublin: Stationery Office

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