This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Low Dose Diphtheria, Tetanus, Acellular Pertussis and Inactivated Poliomyelitis Vaccine (dTaP/IPV)

By registered health care professionals for

Women from 16 weeks of pregnancy in accordance with the pertussis vaccination for pregnant women national immunisation programme and to contacts of pertussis, from 10 years of age, in accordance with PHE Guidelines for the Public Health Management of Pertussis in England and/or PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 79

Change history (see next page)

1. Change history

Version number	Change details	Date
V01.00	New PHE PGD template	15/12/2015
V02.00	Vaccine eligibility changed from 'from 28 weeks of pregnancy' to 'from 20 weeks of pregnancy'	24/03/2016
V03.00	PHE Pertussis PGD amended to: • reflect service specification for vaccine eligibility 'from 16 weeks of pregnancy' rather than 'from 20 weeks of pregnancy' • reference the protocol for ordering storage and handling of vaccines • update wording regarding authorisation in line with agreed PHE PGD template changes and multiple practitioner authorisation sheet, • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	24/03/2017
V04.00	PHE Pertussis PGD amended to: • include additional healthcare practitioners in Section 3, including radiographers to allow for potential commissioning arrangements for immunisation at the time of the fetal anomaly scan • include immunisation of contacts of pertussis in accordance with PHE guidelines • remove the off-label status for use in pregnancy • include additional stability statement for Boostrix-IPV in the storage section • refer to vaccine incident guidelines in off-label and storage sections • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	11/01/2019
V05.00	PHE Pertussis PGD amended to: • amend to off-label section to reflect mention of subcutaneous administration in product literature • clarify wording for dose and frequency of administration for contacts • simplify supplies section • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	18/02/2021

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises Registered healthcare professionals, working within or contracted by the Manx Care, GP Practice or Hospice who are permitted staff groups outlined within the current PGD policy Additionally practitioners: • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD)

Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Indicated for the immunisation of women from 16 weeks of pregnancy in accordance with the recommendations given in Chapter 24 of Immunisation Against Infectious Disease: 'The Green Book' and for the immunisation of contacts of pertussis, from 10 years of age, in accordance with Guidelines for the Public Health Management of Pertussis in England or PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings
Inclusion criteria	• Pregnant women from 16 weeks[1] of pregnancy • Mothers with an infant less than 2 months of age who did not receive pertussis vaccination during their pregnancy • Contacts of pertussis, from 10 years of age, recommended pertussis vaccination in accordance with Guidelines for the Public Health Management of Pertussis in England or PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings
Criteria for exclusion[2] *(continued)*	Individuals for whom no valid consent has been received. Individuals who: • are less than 16 weeks pregnant (with the exception of post-exposure vaccination, at any stage of pregnancy, of contacts at risk of transmitting pertussis to 'vulnerable' individuals) • have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis or poliomyelitis containing vaccine, including any conjugate vaccines where diphtheria or tetanus toxoid is used in the conjugate

[1] From 16 weeks of pregnancy means a gestation of 16 weeks plus 0 days (16^{+0}) or more.

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Criteria for exclusion	• have had a confirmed anaphylactic reaction to any component of the vaccine or residual products from manufacture, these may include formaldehyde, glutaraldehyde, streptomycin, neomycin, polymyxin and bovine serum albumin (refer to relevant SPC) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
Cautions (including any relevant action to be taken)	• The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with the national recommendations • Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	• If less than 16 weeks of pregnancy delay vaccination until indicated unless post-exposure vaccination is indicated in accordance with Guidelines for the Public Health Management of Pertussis in England or PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings • In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged • Seek appropriate advice from the local Screening and Immunisation Team, the local Health Protection Team or the individual's clinician where appropriate • The risk to the individual of not being immunised must be taken into account • Document the reason for exclusion and any action taken in the individual's clinical records • Inform or refer to the GP or a prescriber as appropriate
Action to be taken if patient declines treatment	• Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration • Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications • Document advice given and the decision reached • Inform or refer to the GP or a prescriber as appropriate

8. Details of the medicine

Name, form and strength of medicine	Low dose diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed), eg: • Boostrix®-IPV, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV • Repevax®, suspension for injection in pre-filled syringe (reduced antigen content), dTaP/IPV – see Supplies section
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Indicate any off-label use (if relevant)	• Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. • Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route/method of administration	• Administer by intramuscular injection, preferably into deltoid region of the upper arm
Dose and frequency *(continued)*	Single 0.5ml dose per administration **Routine immunisation in pregnancy schedule** • A single dose of dTaP/IPV should ideally be administered between 16 weeks and 32 weeks of pregnancy to maximise the likelihood that the baby will be protected from birth. For operational reasons, vaccination is best offered on or after the fetal anomaly scan at around 20 weeks • Women may still be immunised after week 32 of pregnancy but this may not offer as high a level of passive protection to the baby • Vaccination late in pregnancy may, however, directly protect the mother against disease and thereby reduce the risk of exposure to her infant • This vaccine should be offered regardless of prior vaccination status. Vaccination is indicated in each pregnancy • For women who have not received the vaccine in pregnancy, pertussis-containing vaccine can be offered to mothers in the two months following birth ie up until their child receives their first dose of pertussis containing vaccine, to reduce the risk of the mother contracting pertussis in the post-partum period and therefore prevent her from infecting her infant **Public health management of pertussis** • A single dose of dTaP/IPV should be administered to contacts

Dose and frequency	recommended immunisation in accordance with Guidelines for the Public Health Management of Pertussis in England or PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings who have not received a dose of pertussis- containing vaccine in the last five years and no Td/IPV vaccine in the preceding month • A dTaP/IPV dose is recommended at any stage of pregnancy for pertussis contacts (in Group 2 b), c) or d))[3], at increased risk of transmitting to 'vulnerable' individuals (in Group 1)[4], who have not received a pertussis containing vaccine in the last five years, and who happen to be pregnant as well. Where such vaccination of pregnant contacts occurs before 16 weeks of pregnancy, a further dose of pertussis containing vaccine will be required after 16 weeks of pregnancy in accordance with the routine immunisation schedule and at least 4 weeks after the preceding dose
Quantity to be administered	Single 0.5ml dose per administration.
Maximum or minimum treatment period	See dose section above
Storage	• Store at +2°C to +8°C • Store in original packaging in order to protect from light • Do not freeze • Upon removal from the cold chain, Boostrix® -IPV is stable for 8 hours at 21°C • In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance

[3] b) healthcare workers working with infants and pregnant women c) people whose work involves regular, close or prolonged contact with infants too young to be fully vaccinated d) people who share a household with an infant too young to be fully vaccinated

[4] Individuals at increased risk of severe complications ('vulnerable'): • unimmunised infants (born after 32 weeks) less than 2 months of age whose mothers did not receive pertussis vaccine after 16 weeks of pregnancy and at least 2 weeks prior to delivery • unimmunised infants (born < 32 weeks) less than 2 months of age regardless of maternal vaccine status • unimmunised and partially immunised infants (less than 3 doses of vaccine) aged 2 months and above regardless of maternal vaccine status

Adverse effects	• Local reactions following vaccination are very common ie pain, swelling or redness at the injection site. A small painless nodule may form at the injection site. Injection site haematoma, pruritus, warmth and numbness have also been reported • Common adverse reactions include fever, headache, gastrointestinal disturbances (nausea, diarrhoea, vomiting, abdominal pain), arthralgia, myalgia, malaise, and fatigue/asthenia • Hypersensitivity reactions and anaphylaxis can occur but are very rare • A detailed list of adverse reactions is available in the SPC, at the electronic Medicines Compendium website: www.medicines.org.uk
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records (see Appendix C for more information)

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine • Immunisation promotional material may be provided as appropriate: Pregnant? There are many ways to help protect you and your baby. Available from www.gov.uk/government/collections/immunisation
Follow-up advice to be given to patient or carer	• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately • Inform the individual/parent/carer of possible side effects and their management • The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction • When administration is postponed advise the individual/parent/carer when to return for vaccination

10. Appendix A

References

1. British National Formulary (BNF) 2019 available online: https://bnf.nice.org.uk
2. Nursing and Midwifery (2018) "The code" available online: https://www.nmc.org.uk
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: https://www.medicines.org.uk

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- Summary of Product Characteristic for Boostrix®-IPV, GlaxoSmithKline. 19 January 2018. http://www.medicines.org.uk/emc/medicine/28679
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- Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 13 November 2017. https://www.gov.uk/government/publications/vaccination-of- individuals-with-uncertain-or-incomplete-immunisation-status
- Guidelines for the Public Health Management of Pertussis in England. Published May 2018. https://www.gov.uk/government/publications/pertussis-guidelines- for-public-health-management
- PHE Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings. Updated 2 November 2016. https://www.gov.uk/government/publications/pertussis-guidelines- for-public-health-management-in-a-healthcare-setting

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- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health. 20 March 2013. https://www.gov.uk/government/publications/guidance-on-the-safe- management-of-healthcare-waste
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for- registered-healthcare-practitioners

- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources

11. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

12. Appendix C

Route/method of administration	• When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records • For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see 'The Green Book' Chapter 4) • Boostrix-IPV® is the recommended product for the vaccination for pregnant women programme. Repevax® (dTaP/IPV) may be used as an alternative if Boostrix-IPV® (dTaP/IPV) vaccine is not available. Either vaccine is recommended for the immunisation of contacts of pertussis • The vaccine's normal appearance is a uniform cloudy, white suspension which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine • The vaccine should not be used if discoloured or foreign particles are present in the suspension • The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)

Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended for eligible individuals even if the antibody response may be limited. May be given at the same time as other vaccines A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Records to be kept	Record: • that valid informed consent was given; • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD • Records should be signed and dated (or password controlled immunisers record on e-records) • All records should be clear, legible and contemporaneous • This information should be recorded in the individual's GP record and the electronic and/or hand-held maternity record (if available). Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed • The local Child Health Information Services team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy

Special considerations/ additional information	• Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination • Pertussis vaccination is recommended after the fetal anomaly scan to prevent any identified anomalies being inappropriately attributed to vaccination. The fetal anomaly scan usually takes places between 18^{+0} and 20^{+6} weeks gestation. Mothers declining the anomaly scan should continue to be offered pertussis vaccination • If a person has received vaccination for a tetanus-prone wound from week 16 of this pregnancy with a vaccine also containing pertussis antigen then the additional dose in pregnancy using Boostrix®-IPV or Repevax® would not be required, refer to advice in the 'The Green Book' Chapter 30 • Women who have never received (or not completed) a primary schedule of vaccination against diphtheria, tetanus and polio should be offered a single dose of dTaP/IPV in accordance with this PGD. They should then be offered Td/IPV (eg Revaxis®) at appropriate intervals if any subsequent doses of vaccine are needed to complete a three dose primary course. See PHE Vaccination of individuals with uncertain or incomplete immunisation status