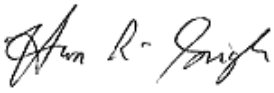
Patient Group Direction (PGD) for the Administration of

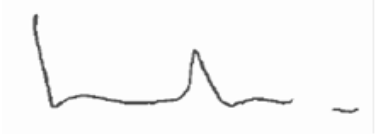
COMBINED DIPTHERIA, TETANUS, ACELLULAR PERTUSSIS AND INACTIVATED POLIOMYELITIS VACCINE (dTaP/IPV) – (Boostrix®-IPV / Repevax®)

by Registered Professionals to Individuals Accessing NHS Services in
Durham, Darlington, Tees, North Cumbria, Northumberland and Tyne & Wear

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

Direction Number: - **NECSAT 2018/001**
Valid from: 1st July 2018
Review date: 1st March 2020
Expiry date: 30th June 2020

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author) (North of England Commissioning Support)	**Sue White** *(Senior Pharmacist)*		27/06/18
Medicines Optimisation Pharmacist (North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		27/06/18
Assistant Medical Director (NHS England, Cumbria and North East)	**Dr James Gossow** *(Senior Doctor)*		27/06/18
Immunisation and Screening Coordinator (NHS England, Cumbria and North East)	**Aline Marron** *(Senior Nurse)*		27/06/18

This PGD has been approved for use in Cumbria, Northumberland, Tyne & Wear by: -			
Title	Name	Signature	Date
Deputy Medical Director (NHS England, Cumbria and North East)	**Dr Jonathan Slade** *(Governance Authorisation)*		28/06/18

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

Immunisation of pregnant and newly delivered women against pertussis (whooping cough)

Objectives of care

- To prevent infectious disease and promote health. To reduce morbidity & mortality and to eradicate disease.

Inclusion criteria (as per Public Health England (PHE) Green Book Chapter 24

Only use those criteria that are specific to your authorised role & competence.
Ensure appropriate consent has been obtained before commencing any vaccination.

- Pregnant women from 16 weeks of each and every pregnancy (optimal time 16-32 weeks)

  Vaccination is probably best offered on or after the foetal anomaly scan at around 20 weeks gestation (see also additional information section).
- Mothers with an infant less than 2 months of age who did not receive pertussis vaccination during their pregnancy (ideally given as soon as possible after birth).
- Pregnant women beyond week 32 of pregnancy up to onset of labour not vaccinated against pertussis during this pregnancy (this offers less passive protection to the baby but offers protection against disease to the mother and thereby reduces risk of exposure to the baby)

Exclusion criteria

General exclusions *(Refer to current Summary of Product Characteristics (SPC) &/or BNF for full list of details)***: -**

- No valid consent (if applicable).
- Pregnant women under 16 weeks of pregnancy (gestation).
- Any pregnant women from 16 weeks of gestation who has already been vaccinated against pertussis during this pregnancy.
- 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.
- Patient is acutely unwell (postpone vaccination until recovered. Minor infections without fever or systemic upset are not reasons to postpone immunisation).
- Any individual who has experienced transient thrombocytopenia, neurological complications or an encephalopathy of unknown aetiology, within 7 days of previous immunisation with a pertussis containing vaccine.
- Confirmed anaphylactic reaction to any component of the vaccine or to any substance carried over from manufacture including neomycin, formaldehyde, glutaraldehyde, streptomycin, polymixin B and bovine serum albumin. **(Practitioners must check the SPC).**
- Confirmed anaphylactic reaction to a previous dose of diphtheria,tetanus,pertussis or poliomyelitis containing vaccines.
- Severe hypersensitivity to any ingredient or component of the vaccine(s) – **(please also refer to precautions section).**
- Unstable neurological condition – defer and consider referral to a specialist
- Individuals with evidence of current neurological deterioration, including poorly controlled epilepsy – refer to specialist.

Refer to current SPC/ Green Book (current on-line version)/ BNF for full list of details

Precautions

- A personal or family history of seizures is not a contraindication to immunisation.
- Individuals with an unstable or progressive neurological disorder including poorly controlled epilepsy, immunisation should be deferred and advice sought from a specialist – see current Green Book Chapter 24 for detailed advice.
- Individuals with immunosuppression and HIV infection (regardless of CD4 count) should still be vaccinated according to the routine recommended schedule. These individuals may not make a full antibody response and re-immunisation should be considered. Specialist advice may be required.
- Hypersensitivity reactions to previous dose of vaccine or component of vaccine:
  - **NB**. "Local adverse reactions that generally start within a few hours of the injection and are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens."

Action if excluded

- Discuss with or refer to clinician/doctor. Ensure all actions/decisions are documented.
- The risk to the individual of not being immunised must be taken into account.
- If postponement due to acute illness, arrange a future date for immunisation.

Circumstances in which further advice should be sought from a doctor and/or specialist

- Patient meeting the exclusion criteria
- Patient requires additional information in order to decide whether or not to have the vaccination
- Unstable or progressive neurological disorder
- Boostrix®-IPV and Repevax® should be administered with caution to subjects with thrombocytopenia or a bleeding disorder

Action if vaccination refused

- Ensure patient/guardian/carer fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications If postponement due to acute illness, arrange a future date for immunisation
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate

Special Considerations

- Pregnant women should be vaccinated in each pregnancy regardless of previous history to ensure protection of the foetus
- In exceptional circumstances where there is no Boostrix-IPV vaccine when the woman attends for vaccination and it's unlikely she will present again, it would be preferable to give Repevax (dTaP/IPV). Women who become pregnant again, should be offered immunisation during each pregnancy.
- 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 (e.g. 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).

2. Description of treatment

Name, strength & formulation of drug

Low dose diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed)

These include:

- **Boostrix®-IPV** (GSK) – 0.5ml suspension for injection in pre-filled syringe (reduced antigen content), (dTaP/IPV).
  - (A homogenous turbid white suspension should be obtained when shaken)
- **Repevax®** (Sanofi Pasteur) – 0.5ml suspension for injection in pre-filled syringe (reduced antigen content), (dTaP/IPV)

Legal Status:

POM –Prescription Only Medicines

- Boostrix®-IPV is licensed for use in the 3rd trimester of pregnancy and Repevax® is licensed for administration to a pregnant woman on the basis of official recommendations Theuse of these vaccines in pregnancy is off-label, but are recommended by the Joint Committee of Vaccination and Immunisation (JCVI) and Public Health England
- Administration of Boostrix®-IPV by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 24v3 of "The Green Book".
- Repevax® SPC includes consideration of administration by deep subcut injection to individuals with bleeding disorders.

Dosage /Dose range

All ages: Single 0.5ml dose

Route/Method

Intra-muscular (IM) injection is the preferred route (Deltoid region of the upper arm).

- Not to be given intravenously.
- Patients with known bleeding disorders could receive the vaccine by deep subcutaneous route (to reduce the risk of bleeding in line with advice in Green Book). **NB**. Boostrix®-IPV & Repevax® should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. Firm pressure should be applied to the injection site (without rubbing) for at least two minutes.
- If given at the same time as other vaccines it should be given at separate sites, preferably in a different limb.
- Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine.

(Please refer to the manufacturer's SPCs and on line version of the Green Book for detailed information).

Frequency of Administration

PREGNANT WOMEN AND NEW MOTHERS	
16 weeks pregnant to onset of labour	**1 single dose** during each pregnancy
New mother up to 8 weeks after labour	**1 single dose**

Maximum dose

0.5ml

Follow up treatment

- Follow current Green Book recommendations as applicable

  https://www.gov.uk/government/publications/pertussis-the-green-book-chapter-24

3. Further Aspects of Treatment

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See manufacturers SPC for full details / current Green Book online Chapters 15,24,26 & 30

Potential Adverse Effects/ Reactions: - Usually transient and only last a few days after vaccination.

Please be aware of Resuscitation Council Guidelines

Very common & common reactions	Local reactions following vaccination are very common i.e. mild swelling, erythema, pain and redness at injection site. A small painless nodule may form at the injection site. Others include: - Headache, malaise, fatigue, fever, vomiting, nausea, abdominal pain, anorexia and irritability. Also for Repevax: - Arthralgia, asthenia, chills, joint swelling, and myalgia
Uncommon reactions	Decreased appetite, paraesthesia, dizziness, somnolence and asthma. Pruritus, arthralgia, , pyrexia (>39 ºC), cough, diarrhoea, rash, muscle and joint stiffness.
Rare reactions	Extensive swelling of vaccinated limb. Hypersensitivity reactions, such as bronchospasm, angioedema, lymphadenopathy, urticarial lymphadenopathy and anaphylactic reaction

Please note: This list is not exhaustive. A detailed list of adverse reactions for each vaccine is available in the vaccine's Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- Advice on management including anaphylaxis: - Chapter 8 of the Green Book provides detailed advice on managing adverse drug reactions (ADRs) following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor/specialist if appropriate

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and the online Green Book - Chapter 9.

  See manufacturers SPC for details of all potential adverse reactions.

Advice to Patient / Carer (verbal or written)

- Explain protection level expected from vaccine. / Provide a patient information leaflet and discuss as required.
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above and manufacturers SPC).
- Explain procedure for dealing with anaphylaxis /severe allergic reactions.
- Explain the "Out of Hours" procedure. Give date of next vaccine if applicable.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.
- Complete patient-held vaccination record (where applicable)

Arrangements for Referral to Medical Advice

- Doctor/specialist appointment as and when appropriate

Records

In all cases manual records and computerised records should include: -

- Patient's name and date of birth;
- Reason vaccination required;
- Date of administration;
- Confirmation that consent has been obtained;
- Dose, site and route of injection;
- Brand name, batch number and expiry date of vaccine;
- Whom administered by and signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed;
- Support literature given (where applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.

Additional Facilities

- Access to updated online Green Book information; the latest SPC and BNF.
- Store in a refrigerator (+2°C to +8°C). Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline as applicable)

Additional Information

- Before each dose is administered the vaccine should be shaken well to obtain a homogenous turbid white suspension
- Boostrix-IPV® and Repevax® vaccines may be administered at the same time as other vaccines including Influenza
- Boostrix-IPV® (dTaP/IPV) should be reserved for pregnant women and Repevax® (dTaP/IPV) and Infanrix-IPV® (DTaP/IPV) should be used for the pre-school booster vaccine. However, in those exceptional circumstances where there is no Boostrix-IPV® (dTaP/IPV) vaccine when a woman attends for vaccination and it is very unlikely that she will present again, it would be preferable to give Repevax® (dTaP/IPV). If Repevax is not available Infanrix IPV (DtaP/IPV) can be given under PSD, rather than delaying vaccination.
- 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 (FASP) which usually takes places between 18^{+0} and 20^{+6} weeks gestation. Mothers declining the mid-pregnancy anomaly scan should continue to be offered pertussis vaccination.
- 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 (e.g. 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.)

References

- NICE Good Practice Guidance https://www.nice.org.uk/guidance
- Public Health England (April 2013): Immunisation Against Infectious Disease - The "Green Book" Chapters 15 Diphtheria; 24 Pertussis; 26 Poliomyelitis; 30 Tetanus. Accessed on 0606018 at https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book
- Nursing and Midwifery Council (NMC), 2007: Standards for Medicines Management.
- Nursing and Midwifery Council (NMC), 2007: Record Keeping Advice Sheet.
- Nursing and Midwifery Council (NMC), 2008: Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- Resuscitation Council (UK), October 2010: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- GlaxoSmithKline UK, Boostrix®-IPV - Summary of Product Characteristics (SPC), (accessed from Electronic Medicines Compendium https://www.medicines.org.uk/emc/ on 06/06/18).
- Sanofi Pasteur, Repevax® - Summary of Product Characteristics (SPC), (accessed from Electronic Medicines Compendium https://www.medicines.org.uk/emc/ on 06/06/18).
- National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners (Revised February 2018) https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners accessed on 06/06/18
- NICE Medicines Practice Guideline 2 (MPG2)Aug 2013 updated March 2017 https://www.nice.org.uk/Guidance/mpg2 Accessed 06/06/18
- Public Health England Diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis (dTaP/IPV) for pregnant women patient group directive (PGD) template. https://www.england.nhs.uk/south/wp-content/uploads/sites/6/2017/04/ssw-pertussis-in-pregnancy-dtap-ipv-17.pdf Accessed on 07/06/18
- Public Health England; The complete routine immunisation schedule 2016 https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule
- Public Health England; Vaccination of individuals with uncertain or incomplete immunisation status (22/09/15). https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status
- Public Health England; Change in the timing of pertussis vaccine in pregnancy letter Gateway number:2016-063 https://www.england.nhs.uk/south/wp-content/uploads/sites/6/2016/09/timing-pertussis-vacc-pregnancy.pdf Accessed 06/06/18

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically authorised by their clinical lead/supervisor/manager may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists
State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.		

Qualifications required (professional registration applies to specific professions**)**

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council

Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the HPA National minimum standards in immunisation training 2005 either through training or professional competence ensuring that annual training is offered to all staff
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and *Immunisation Against Infectious Disease* (Green Book online version).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

Continued training requirements (applies to all staff)

- Annual attendance at an update on resuscitation skills and the management of anaphylaxis within the community/primary care **(mandatory).**
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation **(recommended).**
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:-_____

I have read and understood the Patient Group Direction.

COMBINED DIPTHERIA, TETANUS, ACELLULAR PERTUSSIS AND INACTIVATED POLIOMYELITIS (dTaP/IPV) VACCINE (Boostrix®-IPV / Repevax®)

I agree to administer Boostrix®-IPV / Repevax® vaccines only in accordance with this Patient Group Direction (NECSAT 2018/001)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

I agree that the above named healthcare professional is authorised to administer medicines in accordance with this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from: 1st July 2018	Review Date: - March 2020	**Expiry Date: - 30th June 2020**

Management & Monitoring of Patient Group Direction NECSAT 2018/001

Combined diptheria, tetanus, acellular pertussis and inactivated poliomyelitis (dTaP/IPV) vaccine (Boostrix®-IPV / Repevax®)

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

Combined diptheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (Boostrix®-IPV / Repevax®) under the Patient Group Direction (NECSAT 2018/001)

PGD Valid from date: 1st July 2018 **PGD Expiry Date:** 30th June 2020

Healthcare Professional			**Authorised by:**		
Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

PGD Valid from: 1st July 2018	Review Date: - March 2020	**Expiry Date: - 30th June 2020**