<table>
<thead>
<tr>
<th><strong>Document Title:</strong></th>
<th>Patient Group Direction for Combined Low Dose Diphtheria, Tetanus, Acellular Pertussis and Inactivated Polio Vaccine (dTaP/IPV - REPEVAX / DTaP/IPV INFANRIX IPV)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Area Team Ref.:</strong></td>
<td>PGD</td>
</tr>
<tr>
<td><strong>Version No.:</strong></td>
<td>5/2014</td>
</tr>
<tr>
<td><strong>Author:</strong></td>
<td>Hitesh Patel Pharmaceutical Adviser</td>
</tr>
<tr>
<td><strong>Owner:</strong></td>
<td>Rebecca Woods, Head of Public Health Commissioning</td>
</tr>
<tr>
<td><strong>File Reference:</strong></td>
<td>I:\NHS_ENGLAND\AngleseyHouse\Commissioning Directorate\Primary Care &amp; Specialised Commissioning\Public Health\Immunisation\2014-15\10) PGDs\Approved</td>
</tr>
<tr>
<td><strong>Document Overseeing Group:</strong></td>
<td>PGD Working Group</td>
</tr>
<tr>
<td><strong>Placement in Framework:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Approval Level:</strong></td>
<td>Medicines Management Committee</td>
</tr>
<tr>
<td><strong>Date of Approval:</strong></td>
<td>Nov 2014</td>
</tr>
<tr>
<td><strong>Review Date:</strong></td>
<td>March 2016</td>
</tr>
<tr>
<td><strong>Amendment Dates:</strong></td>
<td>Page(s)</td>
</tr>
</tbody>
</table>

NHS
Patient Group Direction for dTaP/IPV REPEVAX and DTaP/IPV INFANRIX-IPV
Nov 2014  Review March 2016
Patient Group Direction FOR THE ADMINISTRATION OF

COMBINED LOW-DOSE DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS AND INACTIVATED POLIO VACCINE (dTaP/IPV - REPEVAX / DTaP/IPV INFANRIX IPV)

Infanrix – IPV and Repevax are interchangeable as a booster dose at three years four months of the routine childhood immunisation schedule

Approved By

<table>
<thead>
<tr>
<th>NHS England and Staffordshire Area Team</th>
<th>Name</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Director</td>
<td>Dr Ken Deacon</td>
<td></td>
</tr>
<tr>
<td>LPN Pharmacy Chair</td>
<td>Dr Manir Hussain</td>
<td></td>
</tr>
<tr>
<td>Head of Public Health Commissioning</td>
<td>Rebecca Woods</td>
<td></td>
</tr>
</tbody>
</table>

Date of patient group direction approved: Nov 2014

Date this patient group direction becomes due for review: March 2016 or in response to new local/national guidelines.
STAFF CHARACTERISTICS

- Provider of NHS services within NHS England (Shropshire & Staffordshire Area Team)
- Registered nurse with current NMC registration

Specialist competencies or qualifications:

- The health care professional must have a good understanding of the NICE Good Practice Guidance on Patient Group Directions.

- The NICE competency framework: For health professionals using Patient Group Directions should be used by health care professionals planning to work under this PGD to identify any gaps in their knowledge. The gaps should be addressed before the healthcare professional is authorised to work under this PGD.

- The clinical manager/lead GP/commissioner must have evidence that the health care professional has undertaken training to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.

- The healthcare professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.

- The clinical manager/lead GP must have assessed the competency of the healthcare professional to work to this Patient Group Direction. The NICE competency framework: For health professionals using Patient Group Directions should be used to support this assessment.

- The health care professional must have undertaken training and annual updates in the recognition and treatment of anaphylaxis, including practical in Basic Life Support and has immediate access to an in-date supply of adrenaline 1mg in 1ml (1:1000) at the time of the consultation. (The practitioner must be deemed competent in basic life support and in emergency administration of adrenaline)

- The health care professional must have access to all relevant sources of information e.g. information issued by the Department of Health (Green Book), British National Formulary (BNF), Summary of Product Characteristics (SPC), and the clinical guideline concerning medicine(s) within this Patient Group Direction (PGD).

- The practitioner must be competent and knowledgeable in vaccine cold chain standards.

- The registered health care practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession’s Code of Professional Conduct and Ethics.

YOU MUST BE AUTHORISED BY NAME BY YOUR CLINICAL LEAD UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY
# CLINICAL CONDITION

## Clinical need addressed

A booster vaccination against diphtheria, tetanus, pertussis and poliomyelitis in children aged from 3 years 4 months and under 10 years of age as recommended in the childhood immunisation schedule ([https://www.gov.uk/government/collections/immunisation#childhood-immunisation-schedules](https://www.gov.uk/government/collections/immunisation#childhood-immunisation-schedules)).

## Inclusion criteria

Any child aged 3 years 4 months and under 10 years of age where:

- parent/guardian consent has been given to receive the vaccine
- A primary course of 3 doses of diphtheria, tetanus, pertussis and polio vaccines has previously been given.

## Exclusion criteria

(for full details of interacting medicines refer to current Summary of Product Characteristics (SPC) [www.medicines.org.uk & BNF](https://www.medicines.org.uk))

- Any individual who has had an anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis and inactivated polio containing vaccine or an anaphylactic reaction to neomycin, streptomycin or polymixin B (which may be present in trace amounts).
- No valid consent
- Acute febrile illness (vaccine should be deferred)
- Any individual who has not had a primary course of 3 doses of diphtheria, tetanus, pertussis and polio vaccines
- REPEVAX / INFANRIX –IPV should not be administered to persons who have experienced an encephalopathy of unknown origin within 7 days of previous immunisation with a pertussis-containing vaccine
- REPEVAX should not be administered to individuals with a progressive or unstable neurological disorder, uncontrolled epilepsy or progressive encephalopathy until a treatment regimen has been established and the condition has stabilised.

## Caution/need for further advice /Interactions

REPEVAX® is **NOT** recommended for primary immunisation in children under 10 years of age with an incomplete or no history of a primary course of diphtheria, tetanus toxoid or polio vaccine because it contains low dose diphtheria.

INFANRIX IPV © is **NOT** recommended for primary immunisation in children under 10 years of age either with an incomplete or no history of a primary course of diphtheria, tetanus toxoid or polio vaccine because it contains 3- component acellular pertussis vaccine

Intramuscular injections should be given with care in patients on anticoagulant therapy or suffering from coagulation disorders because of the risk of haemorrhage. In these situations and following official recommendations the administration by deep subcutaneous injection may be considered, although there is a risk of increased local reactions.

The immunogenicity of the vaccine could be reduced by immunosuppressive treatment or immunodeficiency. It is recommended to postpone the vaccination until the end of such disease or treatment if practical.

When concomitant administration with other vaccine(s) is necessary the vaccines must be given at different injection sites, preferably into different limbs. If given in the same limb the injection sites should be at least 2.5cm apart.
### Management of excluded patients
- Document in the individual’s notes, advise and counsel accordingly.
- Refer to medical practitioner or seek appropriate advice from a Consultant in Health Protection if necessary
- For individuals temporarily excluded due to acute or febrile illness advise when the vaccine may be given and arrange another appointment.
- The risk to the individual of not being immunised must be taken into account.

### Action for patients not wishing to receive care under this PGD
- Advise the individual about the protective effects of the vaccine, the risks of infection, including potential complications.
- Document action and advice given (record declined vaccine in the individuals clinical record).
- Refer to doctor or independent prescriber.

### Treatment and Drug details

#### Name form and strength of medicine
Adsorbed low dose diphtheria, tetanus, acellular pertussis and Inactivated Polio Viruses vaccine.

**dTaP/IPV - REPEVAX** is in the form of a sterile liquid suspension supplied in a single dose (0.5 ml) pre-filled syringe with an elastomer stopper.

**DTaP/IPV - INFANRIX –IPV** is in the form of a sterile liquid suspension supplied in a (0.5ml) prefilled syringe with a plunger stopper.

#### Legal classification
POM – Prescription only medicine.

#### Black triangle warning
Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme (www.yellowcard.gov.uk).

No

#### Method of obtaining supply
Order through the ImmForm website ([www.immform.dh.gov.uk](http://www.immform.dh.gov.uk))

#### Site for treatment
- GP surgeries
- Health Centres

#### Route/method
**Repevax** is routinely given by intramuscular injection into the deltoid region

**Infanrix-IPV** is routinely given by intramuscular injection into the deltoid region

Vaccination by deep subcutaneous route should be reserved **only** for individuals with a bleeding disorder.

Vaccine can be given at the same time as other vaccines Preferably in different limbs or at least 2.5cms from the concomitant immunisation.

#### Dose
0.5ml (single dose)

N.B. Shake vaccine gently immediately before administration

#### Number of times treatment may be administered
A single booster dose should be administered for children aged 3 years and 4 months and under 10 years old

#### Quantity to be supplied or administered
0.5ml – Single dose
### Side effects

**Full details of side effects are available in the SPC.**

www.medicines.org.uk

**Suspected adverse reactions to drugs including vaccines should be reported on the yellow card available at the back of the BNF. Also at www.yellowcard.gov.uk**

Common reactions include:
- fever ≥38.0°C
- pain, redness and swelling at the injection site
- crying abnormal, irritability, restlessness
- Diarrhoea, vomiting, nausea

For full list of possible adverse reactions see product information leaflet / SPC

### Additional Information (including storage and disposal)

- Store in a refrigerator (+2°C to +8°C)
- Do not freeze
- Store in original packaging
- Protect from light
- Equipment used for vaccination should be disposed of by placing in a proper, puncture-resistant ‘sharps’ box according to local authority regulations and guidance in Health Technical Memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)

### Advice to patient/carer

**BEFORE TREATMENT:**

- Advise parent/guardian of possible side effects. For full details see product’s summary of product characteristics. Advise action to be taken if side effects are experienced

**AFTER TREATMENT:**

- Provide patient information leaflet
- Advise parent/guardian about next scheduled vaccination

### Follow up

Inform possible side effects and their management. Give advice on temperature control

- Local reactions pain, swelling and redness at the injection site are common. (a small painless nodule may form at the injection site this usually disappears)
- Any serious adverse reaction to the vaccine should be documented in a child’s health records and on their medical records. GP should also be informed.

### Suspected adverse reactions

Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations.

All serious suspected reactions following vaccination should be documented in the patient’s medical record and reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card scheme at http://yellowcard.mhra.gov.uk/

### Error reporting

Any incidents or near-miss issues must be reported via the organisation’s internal reporting system

### RECORD KEEPING

**Documentation needed/treatment records to be kept for audit purposes**

- Patient’s name, address, date of birth and registered GP
- Record of informed consent
A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.

- Manufacturer, vaccine name, product name, batch number, expiry date
- Dose administered
- Date of administration
- Anatomical site of vaccination
- Route of administration
- Advice given to patient (including advice given if vaccination is declined)
- Details of staff who administered (sign and print name)
- Details of any adverse drug reactions, and action taken including informing GP
- Record as supplied via Patient Group Direction (PGD) in patient’s clinical record

All records should be clear, legible and contemporaneous. This information should be recorded as appropriate in the patient’s General Practitioner record or other patient record, depending on location AND the personal Child Health record (PCHR) – the Red Book.

A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.

If vaccination has been completed by a provider other than the GP practice, timely communication to the GP practice to enable the patient’s record to be updated must be completed. Any noted adverse effects following vaccination must also be reported to the GP practice.

Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient’s 25th birthday, or for 8 years following a child’s death.

Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

- Reconciliation – stock balances should be reconcilable with receipts, administration records and disposal.
Register of practitioners qualified to administer and/or supply

Combined Low-dose Diphtheria, Tetanus, Acellular Pertussis and Inactivated Polio Vaccine (dTaP/IPV – Repevax and DTaP/IPV Infanrix - IPV) under this Patient Group Direction

<table>
<thead>
<tr>
<th>Name of clinical manager/GP Lead/Commissioner</th>
<th>Signature of clinical manager/GP Lead / commissioner</th>
<th>Date:</th>
</tr>
</thead>
</table>

A copy of this page should be retained by the authorising manager for 2 years for audit purposes

Please state clinical area where this PGD is in use

**Healthcare professional individual declaration**

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

- PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.
- It is the responsibility of each professional to practice only within the bounds of their own competence.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

<table>
<thead>
<tr>
<th>Name of professional (please print)</th>
<th>Signature</th>
<th>Authorising Manager (Must sign against each entry)</th>
<th>Date of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The clinical lead should review competency of authorised practitioners annually.
Authorisation to use this PGD does not remove inherent professional responsibility and accountability

**References**

DOH Immunisation against infectious disease ‘Green Book’ [www.dh.gov.uk](http://www.dh.gov.uk)

Summary of Product Characteristics Repevax [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)

Summary of Product Characteristics Infanrix-IPV [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)

British National Formulary (Oct 2014) [www.bnf.org](http://www.bnf.org)

Acknowledgement: Medicines Management Team, Telford & Wrekin CCG for developing the PGD.