Patient Group Direction For The Administration Of Low Dose Diphtheria, Tetanus And Inactivated Poliomyelitis Vaccine dT/IPV (Revaxis®) By Nurses, Midwives, Health Visitors And Pharmacists Working Within NHS Grampian

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.

Uncontrolled when printed

Version 7
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 2016</td>
<td>November 2014</td>
<td>2 yearly update to new PGD template.</td>
<td></td>
</tr>
<tr>
<td>March 2017</td>
<td>November 2014</td>
<td>Individuals with an incomplete primary vaccination history for tetanus removed as will be covered by PSD.</td>
<td>Inclusion Criteria</td>
</tr>
<tr>
<td>March 2017</td>
<td>November 2014</td>
<td>Information added regarding individuals with incomplete vaccination status.</td>
<td>Dosage/Total Dosage</td>
</tr>
<tr>
<td>April 2017</td>
<td>November 2014</td>
<td>Reference added for the American Academy of Paediatrics.</td>
<td>Route/Method of administration and References</td>
</tr>
</tbody>
</table>

Subject: Patient Group Direction
Identifier: NHSG/PGD/dT/IPV/MGP860
Replaces: NHSG/PGD/dT/IPV/MGP693, Version 6.1
Keyword(s): Patient Group Direction PGD administration low dose diphtheria tetanus inactivated poliomyelitis vaccine dT/IPV Revaxis nurses midwives health visitors pharmacists immunisation tetanus prone wounds

Policy Statement: It is the responsibility of individual Nurse, Midwife, Health Visitor or Pharmacist and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of patient safety. The expiry date should not be more than 3 years from the date the PGD was authorised.
Document: Drafted: May 2004
Approved: April 2017 (published – May 2017)
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Clinical indication to which this PGD applies

| Definition of situation/condition | This Patient Group Direction (PGD) will authorise Nurses, Midwives, Health Visitors and Pharmacists to administer dT/IPV vaccine to individuals.
This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book and individual Summary of Product Characteristics (SPC). |
| Inclusion criteria | Adults, adolescents and children over ten years of age who require a booster of diphtheria, tetanus or polio immunisation following a primary vaccination course, this will include:
- Adolescents in the 13-18 year age group as part of the UK vaccination schedule as the second booster dose.
- Individuals requiring a booster dose for travel purposes following a travel risk assessment in accordance with Green Book or TRAVAX recommendations.
- Individuals requiring a booster dose for Occupational Health (OHS) purposes following an OHS risk assessment in accordance with Green Book recommendations subjects with tetanus-prone injuries in accordance with advice contained within the Green Book (see Appendix 3). |
| Exclusion criteria | Patients may be administered dT/IPV vaccine under this PGD unless:
- They have had a confirmed anaphylactic reaction or confirmed severe hypersensitivity reaction to neomycin, streptomycin or polymyxin B (which may be present in trace amounts).
- They have a history of severe (i.e. anaphylactic) allergy to latex. Vaccination should be deferred until it can be ascertained that the vaccine to be used is latex-free. Check against SPC or with Pharmacy Medicines Information at ARI (telephone: 01224 552316). For latex allergies other than anaphylactic allergies (e.g. contact allergy to latex) vaccination may proceed as normal. |
- They have had neurological complications following an earlier immunisation against diphtheria and/or tetanus.
- They have had significant local or general allergic reaction to a previous administration of dT/IPV vaccine - a doctor should be consulted.
- They have not completed the primary vaccination course.

### Precautions and special warnings

- Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid wrongly attributing any new symptom or the progression of symptoms to the vaccine.
- Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be immunised in accordance with the routine recommended schedule. These individuals may not have a full antibody response. Re-immunisation should be considered after treatment is finished and recovery has occurred. Specialist advice may be required. Refer to Immunisation Co-ordinator.
- As with any intramuscular (IM) vaccination, the injection should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these subjects.
- In order to minimise the risk of adverse events, dT/IPV vaccine should not be administered to subjects who completed a primary vaccination course or received a booster of a vaccine containing diphtheria or tetanus toxoids within the previous five years.
- The presence of a neurological condition is not a contraindication to immunisation. Where there is evidence of a neurological condition in a child the advice given in the flowchart within the *Green Book chapter 15* should be followed.
- The Joint Committee on Vaccination and Immunisation (JCVI) advises that dT/IPV vaccine may be given to pregnant and breastfeeding women when clinically indicated. This advice differs from that in the summary of product characteristics for dT/IPV vaccine which states that vaccination of pregnant women should only occur if considered urgent to boost immunity. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated virus or bacterial vaccines or toxoids. If a health care worker thinks that the vaccine is contraindicated, he/she should verify this by consulting with a paediatrician or Immunisation Co-ordinator NHS Grampian.
- There will be very few occasions when deferral of immunisation is required. Deferral leaves the individual unprotected; the period of deferral should be minimised so that immunisation can commence as soon as possible. If a specialist recommends deferral this should be clearly communicated to the General Practitioner and he or she must be informed as soon as the child is fit for immunisation.
- Systemic and local reactions following a previous immunisation.
- The Green Book gives advice on the immunisation of children with a history of a severe or mild systemic or local reaction within 72 hours of a preceding vaccine.
- Children who have had a severe reaction to a previous immunisation should be discussed with a doctor where appropriate.

<table>
<thead>
<tr>
<th>Referral criteria</th>
<th>Patients who fall into the categories detailed in the exclusion criteria.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Action if excluded from treatment</th>
<th>Medical advice should be sought – refer to General Practitioner/Consultant (relevant medical practitioner). When administration is postponed advise the patient/parent/guardian/person with parental responsibility when to return for vaccination. The reason why the patient was excluded under the PGD will be documented in the patient’s medical notes.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Action if patient declines treatment</th>
<th>The patient/parent/guardian/person with parental responsibility should be advised of the risks of not having the vaccination and given advice regarding minimisation of risk and where vaccination can be arranged. Record outcome in Patient Medication Record if appropriate and refer the patient to their General Practitioner/Consultant (relevant medical practitioner).</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Consent</th>
<th>Prior to the administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG “Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions”. See link below. <a href="http://intranet.grampian.scot.nhs.uk/ccc_nhsg/15692.html?MenuID=460&amp;">http://intranet.grampian.scot.nhs.uk/ccc_nhsg/15692.html?MenuID=460&amp;</a></th>
</tr>
</thead>
</table>
**Description of treatment available under the PGD**

<table>
<thead>
<tr>
<th>Name of medicine</th>
<th>Low dose diphtheria, tetanus and inactivated poliomyelitis vaccine (dT/IPV) this is available as Revaxis&lt;sup&gt;®&lt;/sup&gt;.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal status</td>
<td>Revaxis&lt;sup&gt;®&lt;/sup&gt; is a Prescription-only Medicine (PoM).</td>
</tr>
<tr>
<td>Form/Strength</td>
<td>Suspension for injection containing purified diphtheria toxoid, purified tetanus toxoid and three strains of inactivated poliovirus. It is supplied as a 0.5mL pre-filled syringe.</td>
</tr>
</tbody>
</table>
| Route/Method of administration | This vaccine should **not** be given by the intravenous or intradermal routes under any circumstances.  
Administration should be given by **intramuscular (IM) injection**, preferably into deltoid region of the upper arm.  
Administration should be given with caution in patients with thrombocytopenia or a bleeding disorder since bleeding may follow IM injection. In these patients, vaccination can be administered by deep subcutaneous injection to reduce the risk of bleeding although there is an increased risk of local reactions (Green Book recommendation).  
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.  
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 (American Academy of Paediatrics 2003). The site at which each vaccine was given should be noted in the individual’s records.  
The vaccine should be well shaken before use and must be visually inspected for foreign particles or variation of physical aspect before use. In the event of these criteria not being met the vaccine should be discarded into a blue lidded bin labelled - medicinal waste products for yellow stream waste disposal.  
The vaccine must be used immediately. |
<table>
<thead>
<tr>
<th><strong>Dosage/Total Dose</strong></th>
<th>Children over 10 years old and adults who have been fully immunised according to the immunisation schedule (second booster dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose:</strong></td>
<td>1 x 0.5mL booster dose</td>
</tr>
</tbody>
</table>

**10 year booster of vaccine given for travel**

| **Dose:**             | 1 x 0.5mL booster dose                                                                        |

<table>
<thead>
<tr>
<th><strong>Tetanus-prone injuries (See The Green Book and Appendix 3)</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose:</strong></td>
<td>1 x 0.5mL booster dose</td>
</tr>
</tbody>
</table>

**N.B.** For patients presenting with an unknown or incomplete immunisation history refer to the “Vaccination of Individuals with uncertain or incomplete immunisation status”. If further guidance is required after consulting the above contact the NHSG Public Health Team.

**Duration of treatment**

| **1 x 0.5mL booster dose.** |

**Storage requirements**

| Store in a refrigerator at +2°C to +8°C. |
| Store in original packaging in order to protect from light. |
| Do not freeze. |

**Follow-up (if applicable)**

| Vaccine recipients should remain under observation until they have been seen to recover from the procedure. It is not possible to specify an exact length of time, but patients should remain on the premises for at least 10 -15 minutes. Patients should not leave if they are feeling at all unwell without speaking to the nurse/midwife/health visitor/pharmacist first. If necessary a doctor or the patient’s GP should be contacted for advice. |
| If more serious adverse or persistent effects occur, the patient/parent/guardian/person with parental responsibility should be advised to contact their GP/Accident and Emergency Department/NHS 24. |
| Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied. |
### Advice to patient (Verbal)

Advice should be given on what to expect and what to do for major and minor reactions.

Give date for next vaccine if applicable.

### Advice to patient (Written)

The Patient Information Leaflet (PIL) contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.

Copies of PIL and SPCs for all medicines can be found at [http://www.medicines.org.uk](http://www.medicines.org.uk) or [http://www.mhra.gov.uk/spc-pil/index.htm](http://www.mhra.gov.uk/spc-pil/index.htm)

### Concurrent Medications/Drug Interactions

The vaccine should not be mixed with other vaccines or parenterally administered substances. dT/IPV vaccine may be administered at the same time as other vaccines or immunoglobulins but at a separate injection site and preferably into a different limb. If given at the same time as BCG vaccine, dT/IPV vaccine must be given into a different arm.

Subjects who are taking immunosuppressive agents may not respond adequately to dT/IPV vaccine.

### Identifying and managing possible adverse reactions

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.

The most commonly seen reactions are minor local injection site reactions such as induration, oedema, pain and redness. A small painless nodule may form at the injection site. Gastrointestinal disorders such as nausea and vomiting are common as are a raised temperature, headache and vertigo.

Arthralgia, myalgia, malaise, lymphadenopathy, urticaria, face oedema, asthenia, influenza-like symptoms and Guillain-Barré Syndrome have rarely been reported with this vaccine. Confirmed anaphylaxis occurs very rarely.

This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SPC for details of all potential adverse reactions.
**BNF:**
https://www.medicinescomplete.com/mc/bnf/current/
https://www.medicinescomplete.com/mc/bnfc/current/

**SPCs/PILs:**
https://www.medicines.org.uk/emc/
http://www.mhra.gov.uk/spc-pil/index.htm

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report the reaction to the MHRA using the Yellow Card System.
https://yellowcard.mhra.gov.uk/

**Medical advice in cases of anaphylaxis**

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. Medical advice must be sought as soon as possible from a doctor if any patient develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the patient is deteriorating then an emergency ambulance must be called on 999 or direct via ambulance control or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. (Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals)

**Facilities and supplies required**

The following should be available at sites where the medication is to be administered:

- Appropriate storage facilities or Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit).
- An acceptable level of privacy to respect patient’s right to confidentiality and safety.
- Resuscitation equipment.
- Access to medical support (this may be via the telephone).
- Approved equipment for the disposal of used materials.
- Clean and tidy work areas, including access to hand washing facilities.
- Copies of the current PGD for the medicine specified in the PGD.
- PGD for the administration of Adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals.
### Characteristics of staff authorised to supply/administer medicine under PGD

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Registered Nurses, Midwives and Health Visitors as recognised by the Nursing and Midwifery Council (NMC) and Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).</th>
</tr>
</thead>
</table>
| Specialist competencies    | Be competent to assess the patient's capacity to understand the nature and purpose of the administration in order for the patient to give or refuse consent.  
Has undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD.  
Be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient.  
Is competent in the administration of the drug. |
| Ongoing training and competency | Have attended basic life support training which is required to be updated annually.  
Have undertaken the NHS e-anaphylaxis training session (and annual updates) which covers all aspects of the identification and management of anaphylaxis. This can be accessed via eKSF, or the AT Learning® tool.  
Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.  
The practitioner must be familiar with the SPC for all medicines administered in accordance with this PGD. |
| Professional managers/Lead Nurses will be responsible for | Ensuring that the current PGD is available to staff providing care under this direction.  
Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.  
Maintain up to date record of all staff authorised to administer drug specified in PGD. |
### Documentation

| Authorisation of administration | Nurses, Midwives and Health Visitors working within NHS Grampian can be authorised to administer the drug specified in this PGD by their Professional Manager/Consultant/Practice GPs. Pharmacists working within NHS Grampian can be authorised to administer the drug specified in this PGD by the Director of Pharmacy.  

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD ([Appendix 1](#)).  

A certificate of authorisation ([Appendix 2](#)) signed by the authorising doctor/manager should be supplied. This should be held in the individual practitioners records, or as agreed locally. |
| Record of administration/supply | An electronic or paper record for recording the screening of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include:  

- Name and address of patient  
- Patient CHI No and date of birth  
- Details of parent/guardian, or person with parental responsibility where applicable  
- Consultant/General Practitioner details  
- Risk group, if appropriate  
- Findings of physical examination, if appropriate  
- Exclusion criteria, record why the drug was not administered  
- Reason for giving  
- Consent to the administration (if not obtained elsewhere)  
- Drug manufacturer, batch number and expiry date (Vaccines and injectable medicines)  
- Site where drug administered, dose and route of administration  
- Signature and name in capital letters of practitioner who administered/supplied the drug  
- Date drug given  
- Record of any adverse effects (advise patient’s doctor)  
- If vaccines are given information regarding this administration must be provided to the General Practice and Practitioner Services Division (PSD) for inclusion on the Scottish Immunisation Recall System (SIRS). |
|
These records should be retained:

**For children and young people**, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment.

**For 17 years and over** retain for 6 years after last date of entry, for 3 years after death, or in accordance with local policy, where this is greater than above.

### Audit

All records of the drug specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each H&SCP/practice/service will be responsible for auditing completion of drug forms and collation of data.

### References

Electronic Medicines Compendium  
[http://www.medicines.org.uk](http://www.medicines.org.uk)  
Revaxis® – Date of revision of text 03/12/14, accessed 02/11/16

British National Formulary  
[https://www.medicinescomplete.com/mc/bnf/current/](https://www.medicinescomplete.com/mc/bnf/current/) accessed 02/11/16

British National Formulary for Children  

Immunisations against infectious disease. Edited by Dr David Salisbury, Dr Mary Ramsay & Dr Karen Noakes. HMSO 2006  
**The Green Book**

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:                  Title:
Frances Adamson       Lead Author: Medicines Management Specialist Nurse
Caroline Hind         Pharmacist: Deputy Director of Pharmacy
Dr Diana Webster      Medical Practitioner: Immunisation coordinator and Public
                      Health Consultant
Fiona Browning        Health Protection Nurse Specialist
Rhiannon Sharp        Lead Travel Nurse GO Health

Authorising Managers

Dr Nick Fluck
Medical Director, NHS Grampian

Mr David Pfleger
Director of Pharmacy and Medicines Management, NHS Grampian

Professor Amanda Croft
Executive Director of Nursing, Midwifery and AHPs, NHS Grampian
Health Care Professional Agreement to Administer Medicines Under Patient Group Direction

I: ________________________________ (Insert name)

Working within: ________________________________ e.g. H&SCP, Practice

Agree to administer medicines under the direction contained within the following Patient Group Direction

**Patient Group Direction For The Administration Of Low Dose Diphtheria, Tetanus And Inactivated Poliomyelitis Vaccine dT/IPV (Revaxis®) By Nurses, Midwives, Health Visitors And Pharmacists Working Within NHS Grampian**

I have completed the appropriate training to my professional standards enabling me to administer medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: ________________________________

Print Name: ________________________________

Date: ________________________________

Professional Registration No: ________________________________
Appendix 2

Certificate Of Authorisation To Administer Medicines Under Patient Group Direction

This authorises: ________________________________

Working within: ________________________________ e.g. H&SCP, Practice

To administer medicines under the following Patient Group Direction

Patient Group Direction For The Administration Of Low Dose Diphtheria, Tetanus And Inactivated Poliomyelitis Vaccine dT/IPV (Revaxis®) By Nurses, Midwives, Health Visitors And Pharmacists Working Within NHS Grampian

The above named person has satisfied the training requirements and is authorised to administer medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction

Signed: ____________________________________ Authorising Manager/Doctor

Print Name: ________________________________

Date: ________________________________
Appendix 3


<table>
<thead>
<tr>
<th>Immunisation Status</th>
<th>Clean wound</th>
<th>Tetanus-prone wound</th>
<th>Human tetanus immunoglobulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fully immunised, i.e. has received a total of five doses of vaccine at appropriate intervals</td>
<td>None required</td>
<td>None required</td>
<td>Only if high risk (See text)</td>
</tr>
<tr>
<td>Primary immunisation complete, boosters incomplete but up to date</td>
<td>None required (unless next dose due soon and convenient to give now)</td>
<td>None required (unless next dose due soon and convenient to give now)</td>
<td>Only if high risk (See text)</td>
</tr>
<tr>
<td>Primary immunisation incomplete or boosters not up to date</td>
<td>A reinforcing dose of vaccine and further doses as required to complete the recommended schedule (to ensure future immunity)</td>
<td>A reinforcing dose of vaccine and further doses as required to complete the recommended schedule (to ensure future immunity)</td>
<td>Yes: one dose of human tetanus immunoglobulin in a different site</td>
</tr>
<tr>
<td>Not immunised or immunisation status not known or uncertain</td>
<td>An immediate dose of vaccine followed, if records confirm the need, by completion of a full five-dose course to ensure future immunity</td>
<td>An immediate dose of vaccine followed, if records confirm the need, by completion of a full five-dose course to ensure future immunity</td>
<td>Yes: one dose of human tetanus immunoglobulin in a different site</td>
</tr>
</tbody>
</table>