Public Health England

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PATIENT GROUP DIRECTION (PGD)

Administration of low dose diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV) to women from 16 weeks of pregnancy in accordance with the pertussis vaccination for pregnant women national immunisation programme.

This PGD is for the administration of low dose diphtheria, tetanus, acellular pertussis and inactivated poliomyelitis vaccine (dTaP/IPV) by currently registered nurses or midwives.

Reference no:	Pertussis PGD
Version no:	v03.00
Valid from:	01 April 2017
Review date:	1 October 2018
Expiry date:	31 March 2019

Public Health England has developed this PGD template to facilitate the delivery of immunisations in the NHS in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended.

Operation of this PGD is the responsibility of commissioners and service providers.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE PGD templates for authorisation can be found from: https://www.gov.uk/government/collections/immunisation

Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

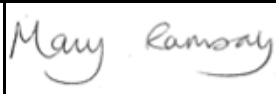
[1] This includes any relevant amendments to legislation (eg 2013 No235, 2015 No.178 and 2015 No.323).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template	15 Dec 2015
V02.00	Vaccine eligibility changed from ‘from 28 weeks of pregnancy’ to ‘from 20 weeks of pregnancy’.	24 Mar 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 Mar 2017

1. PGD template development

This PGD template has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, PHE		28/3/2017
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation, Hepatitis & Blood Safety Department, PHE		24/03/2017
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant – Immunisations, PHE		24/03/2017

This PGD template has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by PHE Medicines Management Group and PHE Quality and Clinical Governance Steering Group.

Acknowledgements

Name	Designation
Gayatri Amirthalingam	Consultant Epidemiologist, Public Health England
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Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)
Gill Marsh	Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire
Lesley McFarlane	Screening and Immunisation Co-ordinator (SIC) NHS England Leicestershire, Lincolnshire and Northamptonshire
Sally Millership	Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team
Sue Mulvenna	Head of Pharmacy - NHS England South West
Graham Munslow	Clinical Screening and Immunisation Manager, NHS England / Public Health England Greater Manchester Health and Social Care partnership
Matthew Olley	Immunisation Manager, Public Health England / NHS England- London Region
Lisa Rees	Medicines Management Pharmacist, Bristol Clinical Commissioning Group
Kelly Stoker	Senior Health Protection Nurse, North East Health Protection Team, Public Health England Centre North East
Sharon Webb	Programme Manager - IDPS , NHS Screening Programmes, Public Health England (Midwife)

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England South (Wessex) authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
This Patient Group Direction (PGD) must only be used by registered healthcare professionals, working within the following CCGS, who have been named and authorised to practice under it.: NHS NORTH HAMPSHIRE CCG NHS FAREHAM AND GOSPORT CCG NHS ISLE OF WIGHT CCG NHS PORTSMOUTH CCG NHS SOUTH EASTERN HAMPSHIRE CCG NHS SOUTHAMPTON CCG NHS WEST HAMPSHIRE CCG NHS DORSET CCG NHS NORTH EAST HAMPSHIRE AND FARNHAM CCG
Limitations to authorisation

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director NHS England (South Region) Wessex	**Dr Elizabeth A Mearns FRCGP**		

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to england.wessexph@nhs.net

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurse or midwife currently registered with the Nursing and Midwifery Council (NMC)
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions) • must be familiar with the vaccine products and alert to changes in their Summary of Product Characteristics, 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 for Immunisation Training (2005) • 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 • must have access to the Patient Group Direction and associated online resources • should fulfil any additional requirements defined by local policy **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**
Continued training requirements	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). Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of women from 16 weeks of pregnancy and for the prevention of pertussis by passive immunity in the neonate in accordance with the recommendations given in Chapter 24 of Immunisation Against Infectious Disease: "The Green Book".
Criteria for inclusion	Pregnant women from 16 weeks[2] of pregnancy. Mothers with an infant less than 2 months of age who did not receive pertussis vaccination during their pregnancy.
Criteria for exclusion[3]	Individuals for whom no valid consent has been received. Individuals who: • are less than 16 weeks pregnant • 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 • 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.
Action to be taken if the patient is excluded	If less than 16 weeks of pregnancy delay vaccination until indicated. 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. In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.

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[2] From 16 weeks of pregnancy means a gestation of 16 weeks plus 0 days (16^{+0}) or more.
[3] Exclusion under this Patient Group Direction does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Action to be taken if the patient or carer 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. In a GP practice setting, inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

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5. Description of treatment

Name, strength & formulation of drug	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
Off-label use	Repevax® is licensed for administration to a pregnant woman on the basis of official recommendations and Boostrix®-IPV is now licensed in the 3rd trimester of pregnancy but either vaccine may be administered from 16 weeks of pregnancy in accordance with recommendations in Chapter 24 of "The Green Book". 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 24 of "The Green Book". 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. 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). 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 Summary of Product Characteristics (SPC) provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk

Dose and frequency of administration	Single 0.5ml dose per administration **Routine Immunisation 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.
Duration of treatment	A single booster dose in each pregnancy
Quantity to be supplied / administered	Single 0.5ml dose per administration.
Supplies	Boostrix-IPV® is the recommended vaccine for this programme. Repevax® (dTaP/IPV) may be used as an alternative if Boostrix-IPV® (dTaP/IPV) vaccine is not available. Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and Green Book Chapter 3).
Storage	Store at +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing 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[4]	Immunological response may be diminished in those receiving immunosuppressive treatment. May be given at the same time as other vaccines.

[4] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Identification & management of adverse reactions[5]	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. Common adverse reactions include fever, irritability, headache, nausea, diarrhoea, vomiting, rash, arthralgia, malaise, fatigue/asthenia, dermatitis, bruising and pruritus. Hypersensitivity reactions, such as bronchospasm, angioedema, urticaria, and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available in the vaccine's Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to patient or carer	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
Patient advice / follow up treatment	Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek medical advice in the event of an adverse reaction. When administration is postponed advise the individual/carer when to return for vaccination.
Special considerations / additional information Continued over page	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. 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. 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.

[5] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

Special considerations / additional information continued	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.
Records	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 Patient Group Direction (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 Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway when vaccine is administered to individuals under 19 years of age. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**dTaP/IPV vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 15, Chapter 26 and Chapter 30. Last updated 19 April 2013. Chapter 24. Last updated 07 April 2016 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristic for Boostrix®-IPV, GlaxoSmithKline. 23 December 2016. http://www.medicines.org.uk/emc/medicine/28679 • Summary of Product Characteristic for Repevax®, Sanofi Pasteur. 18 January 2017. http://www.medicines.org.uk/emc/medicine/15256 • Vaccination against pertussis (whooping cough) for pregnant women: information for healthcare professionals. 22 June 2016 https://www.gov.uk/government/publications/vaccination-against-pertussis-whooping-cough-for-pregnant-women • NHS public health functions agreement 2016-17 Service specification no.1A: Pertussis pregnant women immunisation programme. 5 February 2016 https://www.england.nhs.uk/commissioning/pub-hlth-res/ • Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 30June 2016 https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status **General** • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • British National Formulary (BNF) and British National Formulary for Children (BNF-C) www.BNF.org http://www.evidence.nhs.uk/formulary/bnf/current • National Minimum Standards for Immunisation Training (2005) https://www.gov.uk/government/publications/immunisation-training-national-minimum-standards • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published August 2013. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. January 2014. https://www.nice.org.uk/guidance/mpg2/resources • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2015. https://www.rcn.org.uk/professional-development/publications/pub-005336 • Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines • 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

7. Multiple practitioner authorisation sheet

Pertussis PGD v03.00 Valid from: 01/04/2017 Expiry: 31/03/2019

Practitioner

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **INSERT NAME OF ORGANISATION** for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.