Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Pertussis vaccine Patient Group Direction

for the administration of

low dose diphtheria, tetanus and acellular pertussis-containing vaccine, with or without inactivated poliomyelitis (Tdap or dTaP/IPV)

by registered Healthcare Professionals

to

pregnant women from week 16 of pregnancy, in accordance with the national immunisation programme

or to

pertussis contacts aged 10 years and over in accordance with Guidelines for the Public Health Management of Pertussis in England and Guidelines for the Public Health Management of Pertussis Incidents in Healthcare settings

or for

PTHB Occupational Health Service to use for healthcare staff working with young infants (defined as under 3 months of age) or pregnant women according to WHC (2019) 024

in Powys Teaching Health Board

Version number: PGD 0072F

Reference Number: PGD0072F
Valid from: 01/07/2024
Review Date: 01/01/2027
Expiry Date: 01/07/2027

Change History

Version number	Change details	Date
PSD0008	Initial Issue	1/31/10/05
PSD008-A	Review issue and inclusion of pregnant women	1/10/12(review temporary inclusion of pregnant women on CMO advice)
PGD0072	Conversion to PGD and change of brand to Boostrix-IPV and separation of indications	1/6/2014
PGD0072-A	Review issue and amend inclusion criteria to from 16 weeks as per Welsh Government recommendations	27/1/2017
PGD0072-B	Review issue and use of new PTHB template. Include additional healthcare practitioners, contacts of pertussis, further amendments required as a result of clinical review.	20/04/2020
PGD0072-C	Reviewed in line with PHE • amend to off-label section to reflect mention of subcutaneous administration in product literature • clarify wording for dose and frequency of administration for contacts • simplify supplies section • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	01/04/2021
PGD0072-D	Reviewed in line with UKHSA PGD template v6.00 • replace 'Public Health England' and 'PHE' with 'UKHSA', including branding and updated contact details. • replace NHS England and NHS Improvement (NHSE/I) with NHS England (NHSE) following completion of merger on 1 July 2022 • include a reminder of the need for resuscitation facilities in the event of anaphylaxis • clarify management of pregnant women who have been vaccinated with a pertussis-antigen before and after week 16 of pregnancy, or who have already been infected with whooping cough • clarify management for individuals with a prior history of encephalopathy and encephalitis within 7 days of vaccination	31/03/2023

Version number	Change details	Date
PGD0072-E	Amended to include use in occupational health and reviewed in accordance with WMAS advisory document v6.1. Appendix A updated.	22/12/2023
PGD0072F	Reviewed in line with UKHSA Pertussis vaccine PGD template v7.00 to: • include details of a new licensed vaccine, ADACEL® • recommend ADACEL® is preferentially given over Boostrix-IPV® and Repevax® in the maternal vaccination programme, except where an individual has a history of severe allergy to latex, such as anaphylaxis (see Chapter 6 of the Green Book), or ADACEL® is not locally available at the time of vaccination • remove the recommendation to defer vaccination in individuals with a history of developing encephalopathy or encephalitis within 7 days of receiving a vaccine containing either pertussis, diphtheria, polio or tetanus and where resolution of symptoms took longer than 7 days, in line with Chapter 30 of the Green Book • administration in those with a prior history of encephalopathy or encephalitis as outlined above is off-label but in line with Green Book recommendations • include updated temperature excursion information • include minor rewording, formatting and layout changes for clarity and consistency with the UKHSA PGD template Revised in line with WMAS Advisory document v7.0.	01/07/2024

This Powys Teaching Health Board (PTHB) PGD is based on Pertussis vaccine PGD template v7.00 developed by the following on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy (also ratified by the UKHSA Medicines Governance Committee).

The template has been adapted for use in PTHB, and advice from the WMAS Advisory document v7.0 has been incorporated.

Developed by the following health professionals on behalf of the UKHSA:

Developed By:	Name
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist – Immunisation and Vaccine Preventable Diseases Division, UKHSA
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Expert panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	6/20/2024
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	6/13/2024
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	6/20/2024
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	6/13/2024

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.

Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD before working according to it. Those using this PGD must ensure that it is organisationally authorised and signed 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.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires. Practitioners and organisations must check that they are using the current version of the PGD.

[1] This includes any relevant amendments to legislation

PGD adoption by the provider (Signatures to be determined locally, if relevant)

Name	Job title and organisation	Signature	Date

1. Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working under this PGD must also be a registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics, physiotherapists and radiographers currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply and administration of medicines. Must have completed Patient Group Directions training (available via eLfH PGD eLearning programme. PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • must be competent in the use of PGDs (see NICE Competency framework for healthcare professionals using PGDs). Individuals operating under this PGD must be assessed as competent (see Appendix A) • must be familiar with the vaccine products and alert to changes in their Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the Green Book), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training and online training.

	Please contact PTHB Immunisation coordinator for further information. • 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. Completion of cold chain training (also available via ESR) • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Basic Life Support skills • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Updating at least every 2 years on the administration of low dose diphtheria, tetanus and acellular pertussis-containing vaccine, with or without inactivated poliomyelitis (Tdap or dTaP/IPV). 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 must make a self-declaration of competency on PADR (if relevant). The **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. Compliance with all mandatory NHS training (if relevant). Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and UKHSA 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. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.** **If used in PTHB Occupational Health Service, must be used in line with PTHB Occupational Health Immunisation policy.**

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the • immunisation of women from 16 weeks[2] of pregnancy in accordance with the recommendations given in Chapter 24 of Immunisation Against Infectious Disease: The Green Book or • immunisation of contacts of pertussis, from 10 years of age, in accordance with Guidelines for the Public Health Management of Pertussis in England or Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings, or • PTHB Occupational Health Service to use for the immunisation of Healthcare Staff who have not received a pertussis-containing vaccine in the last 5 years and have regular contact with young infants (defined as under 3 months of age) or pregnant women, according to WHC (2019) 024. **It is the responsibility of the administering healthcare professional to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the vaccination. If there is any reason for concern, seek medical advice.**
Criteria for inclusion	• Pregnant women from 16 weeks of pregnancy • Mothers with an infant less than 2 months of age who did not receive pertussis vaccination during their pregnancy • Contacts of pertussis, from 10 years of age for whom pertussis vaccination is recommended in accordance with Guidelines for the Public Health Management of Pertussis in England or Guidelines

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

	for the Public Health Management of Pertussis Incidents in Healthcare Settings • PTHB Occupational Health Service may use for Healthcare staff who have not received a pertussis-containing vaccine in the last 5 years and have regular contact with young infants (defined as under 3 months of age) or pregnant women, according to WHC (2019) 024 • Medical and drug history taken, no reason for exclusion • Consent given. NB Refer to PTHB Consent to Treatment and Examination Policy
Criteria for exclusion Exclusion under this PGD does not necessarily mean the vaccine is contraindicated, but it would be outside its remit and another form of authorisation will be required	Individuals who have not given valid consent (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not been obtained). For further information on consent, see Chapter 2 of the Green Book. Several resources are available to inform consent (see written information to be given to individual, parent or carer section). Individuals who: • are less than 16 weeks pregnant (unless identified as a contact at risk of transmitting pertussis to vulnerable individuals) • have been given a dose of diphtheria, tetanus, polio and pertussis (DTaP/IPV)/(dTaP/IPV), diphtheria, tetanus and poliomyelitis (Td/IPV) or diphtheria, tetanus and pertussis (Tdap)-containing vaccine in the last 4 weeks • 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 vaccine component or residue from the manufacturing process, including latex, 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) • are defined as a contact of pertussis, aged under 10 years and are unimmunised or partially immunised. Refer to the dTaP/IPV PGD 0073 and DTaP/IPV/Hib/HepB PGD 0141 as required to bring vaccination up to date.

	• have an unstable neurological condition, including uncontrolled epilepsy, without an identifiable cause • are being considered for immunisation by PTHB Occupational health service due to the staff member having regular contact with young infants (defined as under 3 months of age) or pregnant women, according to WHC (2019) 024, and have received a pertussis-containing vaccine within the last 5 years (NB Healthcare staff who are pregnant should be vaccinated as recommended from 16 weeks of pregnancy in accordance with the national immunisation programme) Refer to sections action to be taken if the patient is excluded and action to be taken if the patient or carer declines treatment.
Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). Women who are less than 16 weeks pregnant, requiring protection without delay, such as following a tetanus-prone wound, or in the management of a diphtheria or poliomyelitis exposure should be given Td/IPV instead. Ensure a minimum 4 week gap is observed prior to offering their pertussis vaccine, from week 16 of pregnancy. In cases of inadvertent administration of Revaxis® (Td/IPV), a dose of Tdap (or dTaP/IPV if Tdap is not suitable or otherwise available) should be given as soon as the error is realised, and local procedures for medicines error reporting should be followed. More information can be found in Pertussis (whooping cough) vaccination programme for pregnant women: information for healthcare practitioners. The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination should proceed in accordance with the national recommendations. The tip caps of ADACEL® prefilled syringes contain a natural rubber latex derivative. ADACEL® must not be given to those with a history of severe allergy to latex, such as anaphylaxis-see Green Book Chapter 6. Either Boostrix-IPV® or Repevax® should be offered as an alternative, whichever is available.

	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. Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list) Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • To generic email address: PowysTHB.Safeguarding@wales.nhs.uk And • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads
Action to be taken if the patient is excluded	If less than 16 weeks pregnant, delay vaccination until indicated, unless post-exposure vaccination is required (as outlined elsewhere in this PGD). In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Individuals with an unstable neurological condition should have immunisation deferred to avoid incorrect attribution of any change, whilst balancing the risk of deferral against the risk of preventable infection. Vaccination should be given promptly once the diagnosis is clear, the expected course of the condition is known, or both. In both instances, a PSD must be used. Individuals (who are not employees of PTHB) identified as requiring immunisation against pertussis for solely

	occupational health reasons, in line with Occupational pertussis vaccination of healthcare workers, should be referred back to their employer for appropriate management, as occupational health schemes are not an NHS commissioned service. Should the individual subsequently become eligible under the criteria for inclusion, they may be immunised under this PGD. Seek appropriate advice from the local Screening and Immunisation Team, the local Health Protection Team or the individual's clinician where appropriate. If for PTHB occupational health use, refer to occupational health consultant as necessary and document advice given in the individual's occupational health records. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the patient or carer declines treatment	Informed consent from the individual, or a person legally able to act on the individual's behalf, must be obtained for each administration and recorded appropriately. The patient information leaflet should be available to inform consent. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate. If for PTHB occupational health use, refer to occupational health consultant as necessary and document advice given in the individual's occupational health records. Inform child health if appropriate – if any vaccination is declined for a child under 18 years, child health must be informed and the appropriate form completed. Where appropriate, complete the letter on the WPAS system and send to the GP.

Arrangements for referral for medical advice	Refer to GP, consultant in communicable disease control (CCDC) or the PTHB occupational health consultant for clinical advice as necessary. Document any advice given.

3. Description of treatment

Name, strength and formulation of drug	Low dose diphtheria, tetanus and pertussis (acellular component) vaccine (adsorbed): • ADACEL® suspension for injection in pre-filed syringe (reduced antigen content), Tdap Low dose diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed): • 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 **Except for individuals with a documented history of severe allergy to latex, ADACEL® is the preferred vaccine to offer in the maternal pertussis programme, in line with JCVI advice to offer a non IPV-containing pertussis vaccine.** **Otherwise, if ADACEL® is not locally available to offer at the time of the appointment, Boostrix-IPV® or Repevax® may be given.**
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	Individual Summaries of Product Characteristics (SmPCs) may differ in their licensed indications from official vaccination policy as specified in the Green Book and Welsh Policy. On these occasions, Green Book recommendations should take precedence and provides the rationale for any off-label use. Practitioners using authorised PGDs should also be familiar with the relevant chapters of the Green Book, SmPCs and Welsh Policy, and be constantly alert to any subsequent recommendations from Public Health Wales and/or Welsh Government and other sources of medical information.

	Vaccines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to Vaccine Incident Guidance and All Wales Advisory document on Ordering Storage and Handling of Vaccines and any relevant local policies/guidance. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD. ADACEL®, Boostrix® and Repevax® SPCs all advise vaccination is contraindicated for individuals who developed encephalopathy within 7 days of receiving a vaccine containing pertussis antigen. In line with advice outlined in Chapter 30: neurological conditions (update to Chapter 24 pending), deferral of vaccination should be considered where there is evidence of current neurological deterioration of the condition, to avoid incorrect attribution of any change, whilst balancing the risk of deferral against the risk of preventable infection. Vaccination should be given promptly once the diagnosis is clear, the expected course of the condition is known, or both. Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual, parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.
Route and method of administration	Administer by intramuscular injection, preferably into the deltoid muscle of the upper arm (see Green Book Chapter 4). 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 into different limbs. If given into the same limb, they should be given at least 2.5cm apart. The site at which vaccine was given should be noted in the individual's records. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment

	to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual or carer should be informed about the risk of haematoma from the injection. If the intramuscular route is unsuitable, the vaccine may be administered by deep subcutaneous injection in line with Chapter 4. ADACEL®, Boostrix-IPV® and Repevax® appear as uniform, cloudy white suspensions which may sediment during storage. Shake the prefilled syringe well to uniformly distribute the suspension before administering the vaccine. The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and discard the vaccine in accordance with local procedures. The vaccine SPC provides further guidance on preparation and administration.
Dose and frequency of administration	Single 0.5ml dose per administration. **Routine immunisation in pregnancy schedule** A single dose of Tdap (or dTaP/IPV if ADACEL® is unsuitable or otherwise unavailable) should ideally be administered between 16 weeks and 32 weeks of pregnancy to maximise the likelihood that the baby will be protected from birth. 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.

	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 2 months following birth, up until their child receives their first dose of pertussis-containing vaccine. This is to reduce the risk of the mother contracting pertussis in the post-partum period and passing it on to her infant. If a pregnant woman receives a dose of pertussis-containing vaccine after week 16 of pregnancy for occupational or contact purposes, this dose is considered valid for the maternity vaccine schedule, and no further doses are required in that pregnancy. **Public health management of pertussis** A single dose of dTaP/IPV should be administered to contacts recommended immunisation in accordance with Guidelines for the Public Health Management of Pertussis in England or Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings who have not received a dose of pertussis-containing vaccine in the last 5 years and no Td/IPV vaccine in the preceding 4 weeks. As outlined in the above guidelines, a single dTaP/IPV dose is recommended at any stage of pregnancy for pertussis contacts (in Groups 2b, 2c or 2d)[3], at increased risk of transmitting to vulnerable individuals (in Group 1)[4], who have not received a pertussis-containing vaccine in the last 5 years, and who happen to be pregnant as well. Tdap may also be offered for pregnant individuals, where immunisation is recommended in line with these guidelines. Where such vaccination of pregnant contacts occurs before 16 weeks of pregnancy, a further dose of pertussis-containing vaccine will be required after 16 weeks of pregnancy in accordance with the routine immunisation schedule and at least 4 weeks after the preceding dose.

[3] **Group 2b**:healthcare workers working with infants and pregnant women **Group 2c:** people whose work involves regular, close or prolonged contact with infants too young to be fully vaccinated **Group 2d:** people who share a household with an infant too young to be fully vaccinated

[4] **Group 1 -Individuals at increased risk of severe complications ('vulnerable'):** • unimmunised infants (born after 32 weeks) less than 2 months of age whose mothers did not receive pertussis vaccine after 16 weeks of pregnancy and at least 2 weeks prior to delivery • unimmunised infants (born < 32 weeks) less than 2 months of age regardless of maternal vaccine status • unimmunised and partially immunised infants (less than 3 doses of vaccine) aged 2 months and above regardless of maternal vaccine status

	PTHB Occupational health use for immunisation of Healthcare Staff who have regular contact with young infants (defined as under 3 months of age) or pregnant women, according to WHC (2019) 024. A single dose of dTaP/IPV should be administered to healthcare workers who have not received a pertussis-containing vaccine in the last 5 years.
Duration of treatment	See **Dose and frequency of administration** above
Quantity to be supplied and administered	Single 0.5ml dose per administration.
Supplies	Centrally purchased vaccines for the national immunisation programme for pregnant women can only be ordered via ImmForm and are provided free of charge. Though ADACEL® as a non-IPV containing pertussis vaccine is preferred for the maternal programme, if ADACEL® is not available or otherwise unsuitable, such as in individuals with a severe allergy to latex, offer either Boostrix-IPV® or Repevax®. It is imperative to ensure the individual is offered a suitable and available vaccine containing a pertussis-containing antigen, rather than risk not being immunised against pertussis. Infanrix-hexa® or Infanrix-IPV+Hib® should not be given in the maternity programme as the higher antigenic content increases the likelihood of localised adverse reactions. Supplies for the vaccination of contacts of pertussis should be sourced directly from manufacturers or their wholesalers. Where vaccine cannot be directly sourced from manufacturers or wholesalers, please contact the national immunisation team for further advice. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.
Storage	Store at +2°C to +8°C. Store in original packaging to protect from light. Do not freeze.

	Following a single occurrence of a temperature excursion, stability data indicates the vaccine components of both ADACEL® and Repevax® remain stable at temperatures up to +25°C for 72 hours. Upon removal from refrigeration, Boostrix-IPV® is stable for 8 hours at +21°C. If the vaccines are unused during this period, they should be discarded. This information is only intended to guide healthcare professionals in the event of temporary temperature excursions. In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance and contact the manufacturer if specific advice on management of the temperature excursion is required. Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation Coordinator (Powys.Immunisations@wales.nhs.uk), and via PTHB Datix reporting system Once for Wales Reporting System.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local authority arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended for eligible individuals even if the antibody response may be limited. Being inactivated vaccines, ADACEL®, Boostrix-IPV® and Repevax® may be given at the same time as other vaccines.

	A detailed list of drug interactions associated with the vaccines are available from the product's SPC.
Identification and management of adverse reactions	Local reactions following vaccination are very common, such as pain, swelling or redness at the injection site. Headache and fatigue are also very commonly reported. Nausea, arthralgia and myalgia are very commonly reported side effects of Repevax®. Generalised aching or muscle weakness and diarrhoea are very commonly reported side effects specific to ADACEL®. Common adverse reactions include fever and gastrointestinal disturbances (diarrhoea and vomiting). Injection-site haematoma, pruritus, warmth and numbness have also been commonly reported with Boostrix-IPV®. Hypersensitivity reactions and anaphylaxis can occur(unknown frequency). In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone must be available for immediate use. In case of anaphylaxis: - • Refer to adrenaline (epinephrine) PGD 0117 and anaphylaxis policy • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO low dose diphtheria, tetanus and acellular pertussis-containing vaccine (indicating if with or without inactivated poliomyelitis (ie. Tdap OR dTaP/IPV)).** Record brand name in patient records. • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system This list is not exhaustive. A detailed list of adverse reactions is available from the product's SPC.

Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales reporting system.
Written information to be given to individual, parent or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • Pregnancy: how to help protect you and your baby • Whooping cough: vaccination in pregnancy programme resources For resources in accessible formats and alternative languages, please visit Home – Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC. Further information for printing and website links suitable for patients can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources.
Advice and follow up treatment	As these vaccines also contain antigens against diphtheria and tetanus, vaccination against pertussis offers additional protection against these other diseases. Boostrix-IPV® and Repevax® additionally offer protection against polio. Inform the individual, parent or carer of possible side effects and their management. The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card scheme.

	When administration is postponed, advise the individual, parent or carer when to return for vaccination.
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a working telephone at the time of vaccination. If a pregnant woman received pertussis-containing vaccine before week 16 of her pregnancy, either in error or for occupational or contact reasons, then she should be offered a second dose when she reaches 16 weeks of pregnancy, or around the time of her antenatal fetal anomaly scan. The dose should be repeated to maximise the antibodies that are transferred across the placenta to her unborn baby. If a repeat dose is required, there should be an interval of at least 4 weeks from the previous dose to minimise the risk of local reaction. If a pregnant woman has received a dose of pertussis-containing vaccine after week 16 of pregnancy for occupational or contact reasons, this should be counted as a valid dose and she would not need a repeat dose during that 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 (Revaxis®) at appropriate intervals if any subsequent doses of vaccine are needed to complete a 3 dose primary course. See Vaccination of individuals with uncertain or incomplete immunisation status. If a woman has had confirmed or suspected whooping cough during pregnancy, she should still be offered the pertussis vaccine. Not all women produce sufficiently high levels of antibodies after an infection, to pass on across the placenta to the infant. NB Healthcare staff who are pregnant should be vaccinated as recommended from 16 weeks of pregnancy in accordance with the national immunisation programme. See information above. NB. Consult the PTHB Occupational Health Immunisation policy for staff requiring immunisation.

Records	Record consultation details as required by local procedures. The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate was made in the individual's best interests, in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent if appropriate. • name of individual, address, date of birth and GP with whom the individual is registered • medical and drug history taken, including any allergies and previous adverse events • printed name and signature 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 • any reasons for exclusion or referral, including advice given and actions taken • advice given, including advice given if the individual is excluded or declines immunisation • details of any adverse drug reactions and actions taken • administered via PGD, record PGD version number Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record and both the electronic and hand-held maternity records (if available). Where vaccine is administered outside the GP setting, appropriate health records should be kept and the individual's GP informed. The local Child Health Information Services team (Child Health Records Department) must be notified using the appropriate documentation or pathway as required by any local or contractual arrangement. If a vaccine is administered to a child up to 18 years of age, forward a notification of vaccination given to Child Health Department (based in Llandrindod hospital for children of school age).

	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references	Tdap and dTaP/IPV vaccine

- Immunisation Against Infectious Disease: The Green Book Chapter 15 and Chapter 26, last updated 19 April 2013. Chapter 30, last updated 6 June 2022. 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. Updated 8 August 2023. http://www.medicines.org.uk/emc/medicine/28679
- Summary of Product Characteristic for Repevax®, Sanofi Pasteur. Updated 23 August 2023. https://www.medicines.org.uk/emc/product/5580
- Summary of Product Characteristics for ADACEL®, Sanofi Pasteur. Updated 15 March 2024. Accessed via https://www.medicines.org.uk/emc/product/15553
- Vaccination against pertussis (whooping cough) for pregnant women: information for healthcare practitioners, UKHSA, last updated 6 September 2021. https://www.gov.uk/government/publications/vaccination-against-pertussis-whooping-cough-for-pregnant-women
- Vaccination of individuals with uncertain or incomplete immunisation status, UKHSA. Updated 6 September 2023. https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status
- Guidelines for the Public Health Management of Pertussis in England. Published May 2018. https://www.gov.uk/government/publications/pertussis-guidelines-for-public-health-management
- Guidelines for the Public Health Management of Pertussis Incidents in Healthcare Settings. Updated 2 November 2016. https://www.gov.uk/government/publications/pertussis-guidelines-for-public-health-management-in-a-healthcare-setting
- Pertussis: occupational vaccination of healthcare workers, published 16 July 2019 https://www.gov.uk/government/publications/pertussis-occupational-vaccination-of-healthcare-

	workers/pertussis-occupational-vaccination-of-healthcare-workers • Policy letters available at: WHC (2019) 024: Pertussis – occupational vaccination of healthcare workers **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Updated 27 March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018. https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection. https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration. Updated 7 July 2022. https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition, September 2017. Available from: https://phw.nhs.wales/topics/immunisation-and-vaccines/advisory-document-on-ordering-storage-and-handling-of-vaccines-7th-revision-pdf/ • Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste. 2013. Available from: https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/

	• Advisory document to support the delivery of the Pertussis Vaccine (Tdap or dTaP/IPV) Patient Group Direction (PGD) in accordance with the National Immunisation Programme in Wales Version 7.0 June 2024 • Public Health Wales. Leaflets and accessible vaccination information. Available from: https://phw.nhs.wales/topics/immunisation-and-vaccines/vaccination-accessible-information/ • Welsh Government. Records management code of practice for health and social care 2022. Published 02 March 2022. Available from https://www.gov.wales/managing-health-and-social-care-records-code-practice-2022

Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs 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.

Printed name of health professional	**Signature of health professional**	**Printed name of senior representative authorising health professional**	**Signature of senior representative authorising health professional**	**Date**

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " comments "	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.