UK Health Security Agency

NHS

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Diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, Haemophilus influenzae type b and hepatitis B vaccine (DTaP/IPV/Hib/HepB) Patient Group Direction (PGD)

This PGD is for the administration of diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis, *Haemophilus influenzae* type b and hepatitis B (DTaP/IPV/Hib/HepB) vaccine to individuals from 6 weeks (routinely at 8 weeks) to under 10 years of age in accordance with the national immunisation programme or for the management of cases and contacts identified in an outbreak of polio in accordance with the national polio guidelines: local and regional services and recommendations from the local health protection team.

This PGD is for use by registered healthcare practitioners identified in section 3, subject to any limitations to authorisation detailed in section 2.

Reference no:	DTaP/IPV/Hib/HepB PGD
Version no:	v6.0
Valid from:	1 July 2025
Review date:	30 January 2028
Expiry date:	1 July 2028

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England 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).

Sections 2 and 7 can be edited within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangement of the NHS organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.

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 completing Section 2 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

[1]This includes any relevant amendments to legislation

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 the UKHSA templates for authorisation can be found from: Immunisation patient group direction (PGD) templates

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

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Vaccination Team, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

Change history

Version no	Change details	Date
v1.0 to v4.0	See previous versions of this PGD for details of change history	3 July 2017 to 6 June 2024
v5.0	UKHSA DTaP/IPV/Hib/HepB amended to: • include updated information from the Infanrix®-hexa SPC, including that excipients include phenylalanine • include updated SPC information on shelf life for Vaxelis® when stored outside of refrigerated conditions; increased from 150 hours to 228 hours • recommend either Vaxelis® or Infanrix®-hexa for individuals with a bleeding disorder who require administration by the deep subcutaneous route (off-label) • remove the recommendation to defer vaccination in individuals with a history of developing either encephalopathy or encephalitis with 7 days of receiving a vaccine containing diphtheria, polio, tetanus or pertussis and where resolution of symptoms took longer than 7 days, in line with Chapter 30 of the Green Book • removal of the recommendation to defer vaccination in individuals with a history of seizures associated with fever, within 72 hours of vaccination. Vaccination should only be deferred where there is evidence of current neurological deterioration in children • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change and other UKHSA PGDs • reflect updated references	6 June 2024
v6.0	UKHSA DTaP/IPV/Hib/HepB amended to: • take account of the forthcoming changes to the childhood immunisation schedule, effective 1 January 2026; a fourth dose of hexavalent vaccine is recommended at 18 months of age for those with a date of birth on or after 1 July 2024 • remove the advice for a dose of monovalent hepatitis B at 12 months for children born on or after 1 July 2024, on the selective neonatal hepatitis B pathway. Dried Blood Spot (DBS) testing may be carried out at any point between 12 and 18 months of age • include minor formatting and other revisions to bring the template in line with other UKHSA PGD templates • reflect updated references and guidance • include registered healthcare professionals named in both the Additional Roles Reimbursement Scheme (ARRS) and HMR2012	22 May 2025

1. PGD development

This PGD has been developed by the following health professionals on behalf of UKHSA:

Developed by	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist -Immunisation Programmes, UKHSA		15 May 2025
Doctor	Dr Gayatri Amirthalingam Deputy Director for Immunisation and Vaccine Preventable Diseases Division and Consultant Medical Epidemiologist, UKHSA		15 May 2025
Registered Nurse and Midwife (Chair of Expert Panel)	Greta Hayward Consultant Midwife, Immunisation Programmes, UKHSA		15 May 2025

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee.

Expert Panel

Name	Designation
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Jess Baldasera	Health Protection Practitioner, North East Health Protection Team, Regions Directorate, UKHSA
Helen Beynon	Clinical Advisor, Immunisation Clinical Advice Response Service (CARS), NHSE London
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Helen Eley	Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Advanced Specialist Pharmacist, Medicines Governance (Patient Group Directions and Medicines Mechanisms), NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner / Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Shilan Ghafoor	Medicines Governance Pharmacist, Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board (ICB)
Elizabeth Luckett	Senior Screening and Immunisation Manger, Screening and Immunisation Team – Kent and Medway, NHSE South East
Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Briony Mason	Vaccination Manager, NHSE West Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London

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.

NHSE - Midlands authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Primary care services and/or all organisations commissioned or contracted by NHS England – Midlands to provide immunisation services in: • Derby and Derbyshire • Lincolnshire • Leicester, Leicestershire, and Rutland • Northamptonshire • Nottingham and Nottinghamshire • Herefordshire and Worcestershire • Birmingham and Solihull • Staffordshire and Stoke-on-Trent • Shropshire, Telford, and Wrekin • Black Country • **Coventry and Warwickshire**
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Regional Director of Commissioning, NHS England Midlands	Roz Lindridge		06/06/2025

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

Local enquiries regarding the use of this PGD may be directed to Vaccination Team, NHS England – Midlands, responsible for your area:

East: england.emids-imms@nhs.net

- Derby and Derbyshire
- Lincolnshire
- Leicester, Leicestershire and Rutland
- Northamptonshire
- Nottingham and Nottinghamshire

West: england.wmid-imms@nhs.net

- Herefordshire and Worcestershire
- Birmingham and Solihull
- Staffordshire and Stoke-on-Trent
- Shropshire, Telford and Wrekin
- Black Country
- Coventry and Warwickshire

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	**All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below**. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • dieticians, occupational therapists, paramedics, physiotherapists and podiatrists currently registered with the Health and Care Professions Council (HCPC) Check section 2 (Limitations to authorisation) 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/administration of medicines • must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the 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 • 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 intramuscular injection technique • must be competent in the recognition and management of anaphylaxis • 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	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 the UKHSA, NHS England (NHSE) 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 individuals from 6 weeks (routinely 8 weeks) to under 10 years of age for the prevention of diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b and hepatitis B in accordance with the national immunisation programme and recommendations given in Chapter 15, Chapter 16, Chapter 18, Chapter 24, Chapter 26, and Chapter 30 of Immunisation Against Infectious Disease: the Green Book • individuals who require immunisation in response to an outbreak of polio in accordance with the national polio guidelines: local and regional services guidelines and recommendations from the local health protection team.
Criteria for inclusion	Individuals from 6 weeks to under 10 years of age who: • require a primary course of immunisation against diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b and hepatitis B (including those who do not have a complete or reliable vaccination history, see special considerations and additional information section) • have a tetanus-prone injury and primary immunisation is considered incomplete or immunisation status is not known or uncertain (see the Green Book Chapter 30) • require vaccination in line with the management of cases and contacts of polio in an outbreak in accordance with the national polio guidelines: local and regional services guidelines and recommendations from the local health protection team
Criteria for exclusion[2]	Individuals for whom no valid consent has been received (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 6 weeks of age • are aged 10 years and over • have had a confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b or hepatitis B 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 the manufacturing process, including para-aminobenzoic acid, which may cause bronchospasm (see name, strength and formulation of drug plus the 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 (continued over page)	Facilities for management of anaphylaxis should be available at all vaccination premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK).

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

Cautions including any relevant action to be taken (continued)	The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of preventable infection. Vaccination should be promptly given once either the diagnosis or expected course of the condition (or both) becomes clear. If the child has not been investigated by a specialist, then immunisation should be deferred until a specialist opinion is obtained. If a seizure associated with a fever occurred within 72 hours of a previous immunisation with any component of the vaccine, immunisation should continue as recommended except where a child has evidence of current neurological deterioration, as outlined above (see also special considerations and addition information section). The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. However, vaccination is still recommended. Premature infants should be vaccinated in accordance with the national routine immunisation schedule according to their chronological age. Very premature infants (born ≤28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the child has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48 to 72 hours. If the premature infant was stable at discharge and has no history of apnoea and/or respiratory compromise, further vaccinations can be given in the community setting. 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. Infanrix®-hexa contains a source of phenylalanine. Though phenylalanine may be harmful to individuals with phenylketonuria (PKU), the parent or carer of the individual will be well versed as to the amounts of phenylalanine tolerable in their diet. The National Society for Phenylketonuria (NSPKU) advise the amount of phenylalanine contained in vaccines is negligible and therefore strongly advise individuals with PKU to take up the offer of immunisation.
Action to be taken if the individual is excluded (continued over page)	If aged less than 6 weeks, advise the parent or carer to return for routine immunisation when the infant is 8 weeks of age or over and give an appropriate appointment. Immunisation can be administered to infants from 6 weeks of age if required, for instance if travelling to an endemic country or if there is an increased risk of contracting hepatitis B virus and a dose of HepB vaccine is due. If aged 10 years or over, assess for immunisation with Td/IPV as appropriate (see the Td/IPV PGD). Individuals who have had a confirmed anaphylactic reaction to a previous dose of hexavalent vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management.

Action to be taken if the individual is excluded (continued)	In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician when a vaccine is indicated outside the remit of this PGD, rather than delay immunisation. 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 individual's GP or a prescriber as appropriate.
Action to be taken if the individual, parent 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 and recorded appropriately. Where an individual lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and the decision reached. Inform or refer to the GP as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated), *Haemophilus influenzae* type b (conjugate) and hepatitis B (rDNA) vaccine (adsorbed), DTaP/IPV/Hib/HepB: • Infanrix®-hexa, powder (Hib) in vial and suspension (DTaP/IPV/HepB) for suspension for injection in a pre-filled syringe or vial. The vaccine may contain traces of formaldehyde, neomycin, para-aminobenzoic acid and polymyxin. It contains a source of phenylalanine • Vaxelis® suspension for injection in a pre-filled syringe. The vaccine may contain traces of glutaraldehyde, formaldehyde, neomycin, streptomycin, polymyxin B and bovine serum albumin
Legal category	Prescription only medicine (POM)
Black triangle	No
Off-label use	Administration of Infanrix®-hexa to individuals born before 24 weeks of gestational age or to individuals who are over 36 months of age is off-label but is indicated until 10 years of age under this PGD in accordance with national recommendations for the vaccination of individuals with uncertain or incomplete immunisation status guidance and the relevant chapters of the Green Book. Administration of Vaxelis® to individuals who are over 15 months of age is off-label but is indicated until 10 years of age under this PGD in accordance with national guidance recommendations for the vaccination of individuals with uncertain or incomplete immunisation status and the relevant chapters of the Green Book. Administration of DTaP/IPV/Hib/HepB to individuals who experienced an encephalopathy of unknown cause occurring within 7 days following previous vaccination with pertussis-containing vaccine is off-label. Individuals may be vaccinated under this PGD once the condition has stabilised or the expected course of the condition becomes clear (see cautions), in line with the recommendations in the associated chapters of the Green Book. The SPC for Vaxelis® advises doses should not be administered by deep subcutaneous injection. Administration of either Vaxelis® or Infanrix®-hexa by deep subcutaneous injection to individuals with a bleeding disorder is appropriate where the intramuscular route is unsuitable and is in line with advice in Chapter 4 of the Green Book. The vaccine product SPCs do not make reference to use of DTaP/IPV/Hib/HepB for the management of outbreak, cases or contacts but do include use of the vaccine as a booster and state that the vaccine should be administered in accordance with official recommendations. Vaccination is therefore recommended under this PGD in accordance with the relevant chapters of the Green Book and the national polio guidelines: local and regional services guidelines. The vaccine 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. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD.

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Off-label use (continued)	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 in accordance with national guidance but outside of product licence.
Route and method of administration	Infanrix®-hexa is presented in 2 parts, as DTaP/IPV/HepB suspension for injection and Hib powder, which must be reconstituted in accordance with the manufacturer's instructions prior to administration. Vaxelis® is presented as a suspension for injection in a pre-filled syringe. Administer by intramuscular injection, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid muscle of the upper arm may be used in individuals over one year of age. When administering at the same time as other vaccines, care should be taken to ensure 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 each 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 clinician familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. 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. 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 other treatment is administered. 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, parent or carer should be informed about the risk of haematoma from the injection. For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by the intramuscular route should be given by deep subcutaneous injection in accordance with the recommendations in the Green Book Chapter 4. If the intramuscular route is not considered suitable, the individual may be offered either Infanrix®-hexa or Vaxelis® for administration by deep subcutaneous injection instead (see off-label use). **Infanrix®-hexa** Before reconstitution, the pre-filled syringe may contain a clear liquid with a white deposit, which should be well shaken to obtain a homogenous turbid white suspension. The powder in the vial is reconstituted with the entire contents of the pre-filled syringe, which should be well shaken until the powder has dissolved. The reconstituted vaccine appears as a cloudier suspension than the liquid component alone. The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, discard the vaccine in accordance with local procedures. **Vaxelis®** Shake the pre-filled syringe gently prior to administration to obtain a homogeneous, whitish, cloudy suspension. The suspension should be

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Route and method of administration (continued)	inspected prior to preparation and administration, for foreign particulate matter and other variation of expected appearance . Should either occur, discard the pre-filled syringe in accordance with local procedures. Further guidance on preparation and administration of either vaccine may be found in the respective SPC.
Dose and frequency of administration	Single 0.5ml dose per administration **Routine childhood immunisation schedule** The national recommendation for infants and young children is for a 4 dose course of DTaP/IPV/Hib/HepB. DTaP/IPV/Hib/HepB 0.5ml should ideally be given at: • first primary immunisation visit (usually at age 8 weeks*) • second primary immunisation visit (usually at age 12 weeks) • third primary immunisation visit (usually at age 16 weeks) • fourth dose at 18 months (from 1 January 2026, for children born on or after 1 July 2024) *Note: immunisation may be brought forward to commence no earlier than 6 weeks of age and an interval of not less than 3 weeks (for one dose only) when required, for instance due to impending travel to an endemic country. A 4 week interval is otherwise required. Children born on or before 30 June 2024 should continue to be offered a dose of Hib at one year of age, as Hib/MenC. Once Menitorix® is no longer available, these children should be offered their Hib dose as the hexavalent vaccine from one year of age. See the Hib/MenC PGD and the routine childhood vaccination schedule letter for further information. Other diphtheria, tetanus, pertussis and polio-containing vaccines are recommended for subsequent routine boosters to complete immunisation, in accordance with national recommendations. **Vaccination of individuals with incomplete immunisation status** When primary vaccination has been delayed, the individual should be immunised at the earliest opportunity. If the primary course is interrupted it should be resumed but not repeated, allowing an interval of 4 weeks between remaining doses. From 1 January 2026, an interval of 4 weeks should be observed between the first 3 primary doses, with the fourth dose offered at 18 months of age. If the individual presents late for their fourth dose, the hexavalent dose should be offered to ensure the individual receives a dose of Hib over the age of one year. If they have received at least one of their primary doses of hexavalent vaccine over one year of age, the additional hexavalent dose offer at 18 months is not needed. Provided it has been at least one year since the last hexavalent dose and that at least one hexavalent dose has been given over the age of one year, the routine dTaP/IPV booster may be given at the scheduled 3 years 4 month visit. Refer to the dTaP/IPV PGD. Individuals who commenced but did not complete a course of multivalent DTaP-containing vaccine (or equivalent) should be managed in line with vaccination of individuals with uncertain or incomplete immunisation status. Note it may be appropriate to discount any previous doses given in countries

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Dose and frequency of administration (continued)	other than the UK and transfer the individual onto the UK schedule, as appropriate to their age. **Management of tetanus-prone wounds** Individuals with incomplete or uncertain history of tetanus immunisation should be vaccinated in accordance with the recommendations in the Green Book Chapter 30, Table 30.1. Individuals may also require human tetanus immunoglobulin (see the Green Book Chapter 30). This PGD does not cover the administration of immunoglobulin. **Immunisation of infants at risk of hepatitis B born on or after 1 July 2024** Infants born to women living with hepatitis B infection should receive monovalent hepatitis B (HepB) vaccine (see HepB PGD) at birth and at 4 weeks of age, followed by 3 doses of DTaP/IPV/Hib/HepB vaccine at 8, 12 and 16 weeks of age. A dose of hexavalent vaccine should be offered at 18 months. The Dried Blood Spot (DBS) test should be carried out at any time between 12 months to 18 months of age to check for hepatitis B infection. Where such infants have received doses of monovalent hepatitis B vaccine scheduled for 0 and 4 weeks late, but before 6 weeks of age, routine primary immunisations should still continue to be scheduled at 8 weeks of age, irrespective of the timing of the late monovalent hepatitis B vaccine dose. This is necessary in order not to delay protection against the other infections. If an infant born to a woman with hepatitis B infection attends after the age of 6 weeks for their first or second dose of hepatitis B vaccine, DTaP/IPV/Hib/HepB should be administered along with the primary immunisation series, with subsequent immunisation visits scheduled at 4-week intervals. In this situation it is very important that the child is tested, from 12 months of age, to check whether they were infected early in life as they missed an early dose of HepB vaccine. Following the recommendation for a fourth dose of hexavalent vaccine at 18 months, there is no longer the requirement for an additional dose of monovalent hepatitis B vaccine at the age of **12 months.** **Where the child is at risk of acquiring hepatitis B infection but was born on or before 30 June 2024**, the child remains eligible for a dose of hepatitis B vaccine at 12 months. DBS testing should also be carried out at the same time. See the HepB PGD for more information. **Management of cases and contacts of polio outbreak** Cases and contacts of polio should be managed in accordance with national polio guidelines: local and regional services guidelines and recommendations from the local health protection team. Management will depend on the level of exposure but may include the administration of a single dose of IPV-containing vaccine, regardless of vaccine history.
Duration of treatment	See dose and frequency of administration
Quantity to be supplied and administered	Single 0.5ml dose per administration.

Supplies	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 the 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. From a microbiological point of view, vaccines should be used as soon as practicably possible once opened and prepared for administration. For Infanrix®-hexa, stability has been demonstrated for up to 8 hours at 21°C. Where the contents have remained unopened throughout, data indicates that for Infanrix®-hexa the vaccine components are stable at temperatures up to 25°C for 72 hours. For Vaxelis®, data indicates the vaccine is stable at temperatures up to 25°C for up to 228 hours. By the end of these periods, the vaccines must be used immediately or discarded. These data are only intended to guide healthcare professionals in case of temporary inadvertent 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 on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste 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 waste disposal arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste.
Drug interactions	The immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended for eligible individuals, even if the antibody response may be limited and is not a reason to withhold vaccination. The individual, parent or carer should be advised of this. May be given at the same time as other vaccines – see identification and management of adverse reactions below. A detailed list of interactions associated with the infant hexavalent vaccine is available from the product's SPC.
Identification and management of adverse reactions (continued over page)	When hepatitis B vaccine is added to DTaP/IPV/Hib vaccine, the frequency and type of adverse reactions experienced remain similar. Prophylactic paracetamol is routinely recommended with co-administered infant doses of DTaP/IPV/Hib/HepB and 4CMenB (see the information about MenB vaccine and paracetamol and the what to expect after vaccinations leaflet on the Immunisation collection webpage for more information).

Identification and management of adverse reactions (continued)	Increased reporting rates of convulsions (with or without fever) and hypotonic hyporesponsive episode (HHE) were observed with concomitant administration of DTaP/IPV/Hib/HepB and PCV13. Prophylactic administration of paracetamol is not routinely recommended where PCV13 and DTaP/IPV/Hib/HepB are co-administered in the absence of 4CMenB. Administration of paracetamol concomitantly with PCV13 vaccination may reduce the immune response to some pneumococcal serotypes in PCV13 in infancy, although this reduction is unlikely to be clinically significant; this effect is not seen when also co-administered with the 4CMenB vaccine. If post immunisation fever does occur after any vaccination visit, then symptoms may be managed with paracetamol. Local reactions following vaccination are very common such as pain, bruising, induration, swelling or redness at the injection site. A small painless nodule may form at the injection site. Other common adverse reactions include fever, abnormal crying, irritability, restlessness, appetite loss, fatigue, diarrhoea, vomiting and nervousness. Hypersensitivity reactions, such as bronchospasm, angioedema, rash, dyspnoea, erythema multiforme, urticaria, and anaphylaxis reaction (such as urticaria, angioedema, oedema, face oedema, shock) can occur but are very rare. A detailed list of adverse reactions is available from the product's SPCs.
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.
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: • a guide to immunisations for babies up to 13 months of age • a quick guide to childhood immunisation for the parents of premature babies • what to expect after vaccinations • using paracetamol to prevent and treat fever after MenB vaccination 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.
Advice and follow up treatment (continued over page)	Inform the individual, parent or carer of possible side effects and their management. Give advice regarding normal reaction to the injection, for example redness and pain at the injection site. Advise the parent or carer about administering prophylactic paracetamol with routine immunisations scheduled at 8 weeks and 12 weeks of age when

Advice and follow up treatment (continued)	DTaP/IPV/Hib/HepB is co-administered with MenB vaccine (see identification and management of adverse reactions). Also refer to the MenB PGD. 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 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. A family history of seizures is not a contraindication to immunisation (see Green Book Chapter 26 and SPCs). When there is a personal or family history of febrile seizures, there is an increased risk of these occurring after any fever, including that caused by immunisation. Seizures associated with fever are rare in the first 6 months of life and most common in the second year of life. After this age, the frequency falls and they are rare after 5 years of age (see the Green Book Chapter 26). Children coming to the UK who have a history of completing immunisation in their country of origin may not have been offered protection against all the antigens currently used in the UK. They may not have received Hib-containing vaccines in their country of origin. Children coming from developing countries, from areas of conflict, or from hard-to-reach population groups may not have been fully immunised. Where there is no reliable history of previous immunisation, it should be assumed that individuals are unimmunised and the full UK recommendations should be followed. Unimmunised or incompletely immunised children require one dose of Hib over the age of one year. It does not matter if the child receives additional Hib at subsequent appointments if the DTaP/IPV/Hib/HepB vaccine is given. If an individual has received vaccination for a tetanus-prone wound with the same vaccine as due for routine immunisation and it was administered at an appropriate interval then the routine immunisation is not required; refer to advice in the Green Book Chapter 30. Tetanus vaccine given at the time of a tetanus-prone injury may not boost immunity early enough to give additional protection within the incubation period of tetanus. Therefore, tetanus vaccine is not considered adequate for treating a tetanus-prone wound. However, this provides an opportunity to ensure the individual is protected against future exposure. Individuals may also require human tetanus immunoglobulin which is not covered by this PGD (see the Green Book Chapter 30).
Records (continued over page)	The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • 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

Records (continued)	• quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if the individual is excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD 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. 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 or pathway as required by any local or contractual arrangement. 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/Hib/HepB vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 15, Chapter 16 Chapter 18, Chapter 24, Chapter 26 and Chapter 30 www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristics for Infanrix®-hexa, GlaxoSmithKline, last updated 7 April 2025, www.medicines.org.uk/emc/product/2586/smpc • Summary of Product Characteristics for Vaxelis®, Sanofi, last updated 9 April 2024 www.medicines.org.uk/emc/product/12264 • Personal communication. Sanofi UK and Ireland Medical Information, received 16 April 2024 • The hexavalent DTaP/IPV/Hib/HepB combination vaccine information for healthcare practitioners, updated 13 May 2024 www.gov.uk/government/publications/hexavalent-combination-vaccine-programme-guidance • Vaccination of individuals with uncertain or incomplete immunisation status, www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status • The National Society for Phenylketonuria (NSPKU) Medical Advisory Panel: Vaccines and PKU, issued 2 October 2024 https://nspku.org/download/vaccines-and-pku/ • National polio guidelines: local and regional services, updated 26 September 2019 assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/833211/National_polio_guidelines_2019.pdf • Changes to the routine childhood schedule letter, published 30 April 2025 https://www.gov.uk/government/publications/changes-to-the-routine-childhood-schedule-letter **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training, published 7 February 2018 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, published 27 March 2017.www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018 www.nice.org.uk/guidance/mpg2/resources • Immunisation Collection www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

DTaP/IPV/Hib/HepB PGD v6.0 Valid from: 1 July 2025 Expiry: 1 July 2028

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

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 PGD 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.