



## Introduction of hexavalent vaccine into the routine childhood immunisation programme for babies born on or after 1 August 2017

As set out in April's edition of Vaccine Update, in late September/early October, Infanrix hexa® (DTaP/IPV/Hib/HepB) will replace both Pediacel® and Infanrix/IPV+Hib® (DTaP/IPV+Hib) for routine childhood immunisations at 8, 12 and 16 weeks of age.

The introduction of a hexavalent vaccine means that as well as being protected against diphtheria, tetanus, pertussis, polio and Hib, babies will also be protected against hepatitis B. The introduction of a vaccine that protects against hepatitis B is an important milestone in the fight against viral hepatitis. World Hepatitis Day takes place on 28 July each year and aims to highlight the global health burden from all forms of viral hepatitis and galvanise efforts to tackle the problem. With the availability of effective vaccines and treatments for hepatitis B and curative treatments for hepatitis C, the World Health Organisation (WHO) goal of elimination of viral hepatitis as a major public health concern now seems to be within our reach.

The introduction of a hepatitis B containing vaccine into the UK routine childhood immunisation programme also fulfils the WHO recommendation that every country should routinely immunise children against hepatitis B, as part of the global strategy to eliminate this virus.

More details on World Hepatitis Day can be found at [weblink 1](#).

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## Changes to the routine and selective immunisation schedules

There is no change to the timing of the routine childhood immunisation schedule with the introduction of the hexavalent vaccine but babies born on or after 1 August 2017 will be offered Infanrix hexa® (DTaP/IPV/Hib/HepB) in place of pentavalent vaccine (DTaP/IPV/Hib) at 8, 12 and 16 weeks of age.

The schedule has changed for the selective neonatal hepatitis B immunisation programme for babies born to hepatitis B infected mothers. These babies will still require a dose of monovalent vaccine immediately after birth and at 4 weeks of age and then follow the routine schedule with hexavalent vaccine (at 8, 12 and 16 weeks of age). They will require a further dose of monovalent hepatitis B vaccine at one year of age and should be tested to exclude infection at the same time (see table one below). A further dose of hepatitis B-containing vaccine at 3 years and 4 months is no longer recommended for those children who have completed their routine primary immunisations with the hexavalent hepatitis B-containing vaccine.

However the pre-school booster visit (for MMR and DTaP/IPV or dTaP/IPV vaccinations) provides an opportunity to check the child has been appropriately managed, i.e. fully immunised against hepatitis B and tested for infection.

**Table one:** Hepatitis B doses in the immunisation schedule for routine childhood and selective neonatal hepatitis B programmes

Age		Routine childhood		Babies born to hepatitis B infected mothers
Birth	✗		✓	Monovalent HepB (Engerix B® or HBvaxPRO Paediatric®) (with HBIG if indicated)
4 weeks	✗		✓	Monovalent HepB (Engerix B® or HBvaxPRO Paediatric®)
8 weeks	✓	DTaP/IPV/Hib/HepB (Infanrix hexa®)	✓	DTaP/IPV/Hib/HepB (Infanrix hexa®)
12 weeks	✓	DTaP/IPV/Hib/HepB (Infanrix hexa®)	✓	DTaP/IPV/Hib/HepB (Infanrix hexa®)
16 weeks	✓	DTaP/IPV/Hib/HepB (Infanrix hexa®)	✓	DTaP/IPV/Hib/HepB (Infanrix hexa®)
1 year	✗		✓	Monovalent HepB (Engerix B® or HBvaxPRO Paediatric®) Test for HBsAg

## Presentation of hexavalent vaccine

Please note, Infanrix hexa® is presented in two parts, a pre-filled syringe and a separate vial containing the powdered Hib component. The vaccine must be reconstituted by adding the contents of the pre-filled syringe to the vial containing the powder. Further details can be found in the Infanrix hexa® Summary of Product Characteristics at [weblink 2](#).



## Vaccine ordering and minimising wastage

Infanrix hexa® is expected to be made available to order through ImmForm from the beginning of September 2017 in readiness for the planned switch over in late September/early October 2017.

To avoid potential wastage, ImmForm customers should aim to run down the volume of DTaP/IPV/Hib (Pediace® and Infanrix-IPV+Hib®) vaccines held in stock and only order the minimum volume to complete vaccination of babies born before 1 August 2017.

Infanrix hexa® should only be given to older babies (ie born before 1 August 2017) if there are no locally held vaccine stocks and no further Pediace® or Infanrix-IPV+Hib® can be ordered through ImmForm.

Following the introduction of Infanrix hexa® for babies born on or after 1 August 2017, in order to avoid any wastage of the existing vaccines used for this programme, any remaining stocks of DTaP/IPV/Hib (Pediace® and Infanrix-IPV+Hib®) should be used for babies who have already started courses with Pediace® or Infanrix-IPV+Hib® (second or third dose). If vaccine supplies still remain, then as a temporary measure, DTaP/IPV/Hib (Pediace® or Infanrix-IPV+Hib®) can be used for pre-school boosting at the age of 3 years and 4 months.

Once DTaP/IPV/Hib stocks are used up, pre-school boosting should revert back to Repevax® (dTaP/IPV).

## Immunisation against infectious disease (the Green Book)

The hepatitis B chapter of the Green Book has been updated and is available at [weblink 3](#).

The new revised chapter sits alongside the current chapter. This chapter has been revised to include the introduction of the combination hexavalent vaccine into the routine childhood immunisation programme for babies born on or after 1 August 2017.

The older chapter includes vaccine recommendations for babies born up to and including 31 July 2017, but for indications other than babies, we recommend that you consult the new chapter that contains the most recent advice.

This is the first chapter in our new format and prints in A4. More details regarding the formatting revisions will be in the regular July edition 267 of Vaccine Update which will be published later this month.

## Training materials for healthcare professionals

Training materials for healthcare professionals, including guidance on the use of hexavalent vaccine in the routine childhood programme, its use in the neonatal selective immunisation programme for babies at risk of maternal to child transmission of hepatitis B and a training slide set in both pdf and powerpoint formats are available at [weblink 4](#).

## Patient Group Directions

Two new national patient group direction (PGD) templates have been developed to support the introduction of DTaP/IPV/Hib/HepB into the routine childhood immunisation programme: a PGD template for the administration of DTaP/IPV/Hib/HepB and a DTaP/IPV/Hib Booster PGD template.

The DTaP/IPV/Hib Booster PGD template has been developed to facilitate the use of remaining supplies of DTaP/IPV/Hib (Pediace® or Infanrix/IPV+Hib®) vaccine, for the pre-school booster, from 3 years and 4 months of age. Such use is recommended to prevent vaccine wastage, should supplies of DTaP/IPV/Hib remain following the introduction of DTaP/IPV/Hib/HepB into the routine childhood immunisation programme.

The existing PHE DTaP/IPV/Hib PGD template remains available and valid until 30 November 2017 to allow for the continued primary immunisation of infants born before 1 August 2017 with DTaP/IPV/Hib, so long as supplies remain available.

The new PGD documents will be published shortly and will be available at [weblink 5](#).





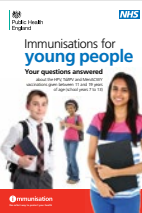
Please note: PHE PGDs should not be downloaded and used by providers directly from the above web-link. Prior to use by immunisers, section two of the PGDs (organisational authorisation) must have been completed as without this the PGD is not lawful or valid. Providers will need to locally obtain organisationally authorised PGDs in accordance with local policy/procedures.

## Leaflets for parents

A range of communication materials for parents is available, see table two below. Leaflets and immunisation schedules which reflect the current childhood schedule, and the updated versions for use following the introduction of Infanrix hexa® are available to order. Ordering for the current versions is expected to close at the end of July 2017.

It is recommended that health professionals order sufficient stock of current leaflets to cover the period up to 31 July 2017 and also have stock available of the new versions ready to distribute from 1 August 2017.

**Table two:** Summary of immunisation publications which have been revised to include the introduction of the hexavalent vaccine

Front cover	Title and H&SC Orderline link	Babies born up to and including 31 July 2017 – Product code/link	Babies born on or after 1 August 2017
	Immunisations for premature babies a quick guide <a href="http://www.orderline.dh.gov.uk/ecom_dh/public/saleproduct.jsf?catalogueCode=31995799B">www.orderline.dh.gov.uk/ecom_dh/public/saleproduct.jsf?catalogueCode=31995799B</a>	2901236	31995799B
	Immunisations for babies up to one year of age – main guide <a href="http://www.orderline.dh.gov.uk/ecom_dh/public/saleproduct.jsf?catalogueCode=3109328B">www.orderline.dh.gov.uk/ecom_dh/public/saleproduct.jsf?catalogueCode=3109328B</a>	3109328	3109328B
	Immunisations for babies at one year of age <a href="http://www.orderline.dh.gov.uk/ecom_dh/public/saleproduct.jsf?catalogueCode=2902127B">www.orderline.dh.gov.uk/ecom_dh/public/saleproduct.jsf?catalogueCode=2902127B</a>	2902127	2902127B
	Immunisations for preschool children <a href="http://www.orderline.dh.gov.uk/ecom_dh/public/saleproduct.jsf?catalogueCode=3197560B">www.orderline.dh.gov.uk/ecom_dh/public/saleproduct.jsf?catalogueCode=3197560B</a>	3197560	3197560B
	Immunisations for young people <a href="https://www.orderline.dh.gov.uk/ecom_dh/public/saleproduct.jsf?catalogueCode=2902598B">https://www.orderline.dh.gov.uk/ecom_dh/public/saleproduct.jsf?catalogueCode=2902598B</a>	2902598	2902598B

All communication materials are available to download and can be ordered from Health & Social Care Orderline at [www.orderline.dh.gov.uk](http://www.orderline.dh.gov.uk)



## The Red Book – Personal Child Health Record Book (PCHR)

The Red Book includes an insert page for babies at increased risk of hepatitis B through perinatal transmission, ie born to mothers identified as being hepatitis B positive during antenatal screening. These babies require an accelerated course of hepatitis B vaccine starting at birth which will now involve giving both monovalent hepatitis B vaccine and hexavalent vaccine. Therefore, the insert page has been amended to include hexavalent vaccine. Other pages of the Red Book have also been updated to take account of the introduction of hexavalent vaccine into the routine programme, but it is particularly important that babies born to hepatitis B infected mothers have a record of their accelerated course of hepatitis B immunisation recorded in the Red Book.

7 parts

### Hepatitis B infant immunisation programme for those at increased risk

\* Please place a sticker (if available) otherwise write in space provided

Surname: \_\_\_\_\_ First names: \_\_\_\_\_ NHS number: \_\_\_\_\_ Unit no: \_\_\_\_\_ Address: \_\_\_\_\_ Sex: M/F \_\_\_\_\_ Post code: \_\_\_\_\_ D.O.B: \_\_\_\_/\_\_\_\_/\_\_\_\_ G.P: \_\_\_\_\_ Code: \_\_\_\_\_ H.V: \_\_\_\_\_ Code: \_\_\_\_\_

Mother's surname: \_\_\_\_\_ Mother's first name: \_\_\_\_\_ Mother's NHS number: \_\_\_\_\_

**Indications for hepatitis B vaccine**

☐ Mother is hepatitis B surface antigen (HBsAg) positive

**Indications for hepatitis B immunoglobulin in addition to vaccine (tick all that apply)**

☐ Mother had acute hepatitis B during pregnancy

☐ Mother is hepatitis B e antigen (HBeAg) positive or e antibody (anti-HBe) negative

☐ Mother has high viral load (HBV DNA  $\geq 1 \times 10^6$  IU/ml)

☐ Mother is HBsAg positive and baby's birth weight  $< 1.5$  kg

**The complete immunisation schedule for babies at increased risk is six doses of hepatitis B containing vaccine**

Age	Immunisation and Follow up required	Date	Vaccine Trade Name	Batch No.	Site	Immuniser (Name in capitals)	Venue
Within 24 hours of birth	Monovalent HepB						
	Hepatitis B immunoglobulin (if needed)						
4 weeks	Monovalent HepB						
8 weeks	DtaPpV/Hb/HepB		also complete page 18 *			also complete page 18	
12 weeks	DtaPpV/Hb/HepB		also complete page 18 *			also complete page 18	
16 weeks	DtaPpV/Hb/HepB		also complete page 18 *			also complete page 18	
At one year	Monovalent HepB		also complete page 19 *			also complete page 19	
	Blood test for HBsAg (refer to specialist if positive)		also complete page 19 *			also complete page 19	

Top copy: remain in PCHR. All subsequent copies return to Immunisation Section as each immunisation is completed

For babies born on or after 01/06/2017

Hepatitis B infant immunisation programme for those at increased risk 18a

The new inserts come in pads of 25 (7 parts per insert). So if you order 5 pads you will have inserts for 125 babies. They are free to order and delivery is also free.

Please order from the Harlow Printing Limited by either:

Email [rebecca@harlowprinting.co.uk](mailto:rebecca@harlowprinting.co.uk)

Or telephone: **0191 496 9735**

Please allow 10 working days for leaflets to arrive after placing an order. Local providers should aim to order enough stock per an order to last approximately 3 months, to ensure delivery costs are not too high.

Do not stockpile quantities that would last 6 months or more. Local providers must pay for orders of the full PCHR. Contact Harlow Printing Limited directly if you would like to set up regular deliveries based on the size of your birth cohort.

## Web links

- web link 1     <http://www.worldhepatitisday.org/en/2017-campaign>
- web link 2     <https://www.medicines.org.uk/emc/medicine/33313>
- web link 3     <https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18>
- web link 4     <https://www.gov.uk/government/publications/hexavalent-combination-vaccine-programme-guidance>
- web link 5     <https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd>