



Public Health  
England

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# The hexavalent DTaP/IPV/Hib/HepB combination vaccine

Information for healthcare practitioners about the introduction of the hexavalent vaccine into the routine infant immunisation programme

# Aim of resource

To provide information to healthcare practitioners about the introduction of a hexavalent DTaP/IPV/Hib/HepB vaccine in order that:

- immunisers are knowledgeable and confident in administering and discussing this vaccine with parents/carers
- high uptake of the routine infant immunisation schedule is sustained as the hexavalent vaccine replaces the pentavalent vaccine

# Content

- Rationale for introducing a hepatitis B containing vaccine into the routine infant immunisation schedule
- Hepatitis B: transmission, symptoms and epidemiology
- Information about the hexavalent vaccine (Infanrix hexa®) and its use
- The neonatal selective immunisation programme for babies at risk of hepatitis B
- Sources of information

# Key points

- Babies born on or after 1<sup>st</sup> August 2017 will be offered a hexavalent DTaP/IPV/Hib/HepB vaccine (Infanrix hexa®) which will protect against hepatitis B
- Hepatitis B is a viral infection that attacks the liver and can cause hepatic necrosis, cirrhosis and an increased risk of developing liver cancer
- Infanrix hexa® is licensed for use in 97 countries and approximately 150 million doses have been given to infants worldwide
- Multiple studies have shown Infanrix hexa® to be safe and highly immunogenic
- Any adverse events experienced are mild to moderate and the same as those following administration of the pentavalent vaccines (Pediace® and Infanrix®-IPV+Hib)
- The infant immunisation schedule remains unchanged at 8,12 and16 weeks

# Introduction of a hexavalent infant vaccine

- From autumn 2017, all babies born on or after 1 August 2017 will receive a hexavalent (6 in 1) vaccine called Infanrix hexa® for their primary immunisations at 8, 12 and 16 weeks
- This hexavalent vaccine includes hepatitis B (HepB)
- It also protects against diphtheria, tetanus, pertussis, poliomyelitis and disease caused by *Haemophilus influenzae* type b (Hib)
- Infanrix hexa® will replace the pentavalent (5 in 1) infant vaccines Infanrix®-IPV+Hib and Pediacel®



# Why is a hepatitis B containing vaccine being offered to all infants?

- In 1992, the World Health Assembly recommended every country should have a universal hepatitis B immunisation programme
- However, as the UK is a low prevalence and low incidence country for hepatitis B, introducing a universal hepatitis B programme using a monovalent hepatitis B vaccine would not have been cost-effective
- Recently, infant combination hepatitis B vaccines (which also protect against diphtheria, tetanus, polio, pertussis and Hib) have become available in the UK
- In 2014, the Joint Committee of Vaccination and Immunisation (JCVI) re-evaluated the benefits and cost-effectiveness of a universal hepatitis B infant immunisation programme in the UK
- They subsequently recommended the use of the hexavalent DTaP/IPV/Hib/HepB combination vaccine for all infants

# What is hepatitis B?

- Hepatitis B is a viral infection that attacks the liver and can cause both acute and chronic disease
- Many new infections with hepatitis B virus (HBV) are sub-clinical or may only cause a flu-like illness
- Mostly asymptomatic in infants
- Acute HBV infection occasionally leads to sudden and severe liver damage which can be fatal
- Chronic HBV infection can result in progressive liver disease
- This can lead to cirrhosis (development of scar tissue) and an increased risk of developing liver cancer

# How is hepatitis B virus (HBV) transmitted?

- HBV is highly transmissible through the exchange of infected blood and bodily fluids
- It can survive outside the body for at least 7 days
- Transmission mostly occurs:
  - through vaginal or anal intercourse
  - as a result of blood-to-blood contact through percutaneous exposure (e.g. sharing of needles and other equipment by people who inject drugs or through 'needlestick' injuries)
  - through perinatal transmission from mother to child
- Transmission has also followed bites from infected persons although this is rare
- Transfusion-associated infection now also rare in UK as blood donors and donations are screened

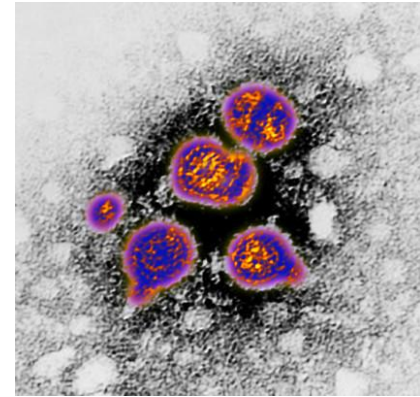


Image courtesy of PHE Colindale



# Clinical presentation

- Many new infections are subclinical showing no signs of infection
- If symptomatic, symptoms of acute infection start insidiously and may present as flu like illness with or without mild fever or symptoms may be non-specific
- Anorexia, nausea, vomiting and aching in the right upper abdomen may be present
- Followed by malaise, decreased appetite, joint pain and jaundice with progressive darkening of urine and lightening of the faeces
- Symptoms may last several weeks to months
- In those with symptoms not suggestive of hepatitis, infection only detected through abnormal liver function tests and/or presence of serological markers of infection e.g. hepatitis B surface antigen (HBsAg)

# Stages of hepatitis B infection

## **Incubation period**

- Average incubation period is 60-90 days but can vary between 40-160 days

## **Infectious period**

- Those with detectable surface antigen (HBsAg) in serum are considered to be infectious
- Those who also have the e-antigen marker (HBeAg) are the most infectious

## **Acute stage**

- Within the first 6 months of infection
- Those who clear the virus during this stage will be immune for life

## **Chronic stage**

- Defined as persistence of HBsAg in the serum for six months or longer
- Referred to as carriers and remain infectious
- Children less than 6 years of age who become infected with hepatitis B virus are the most likely to develop chronic infection

# Treatment and prevention

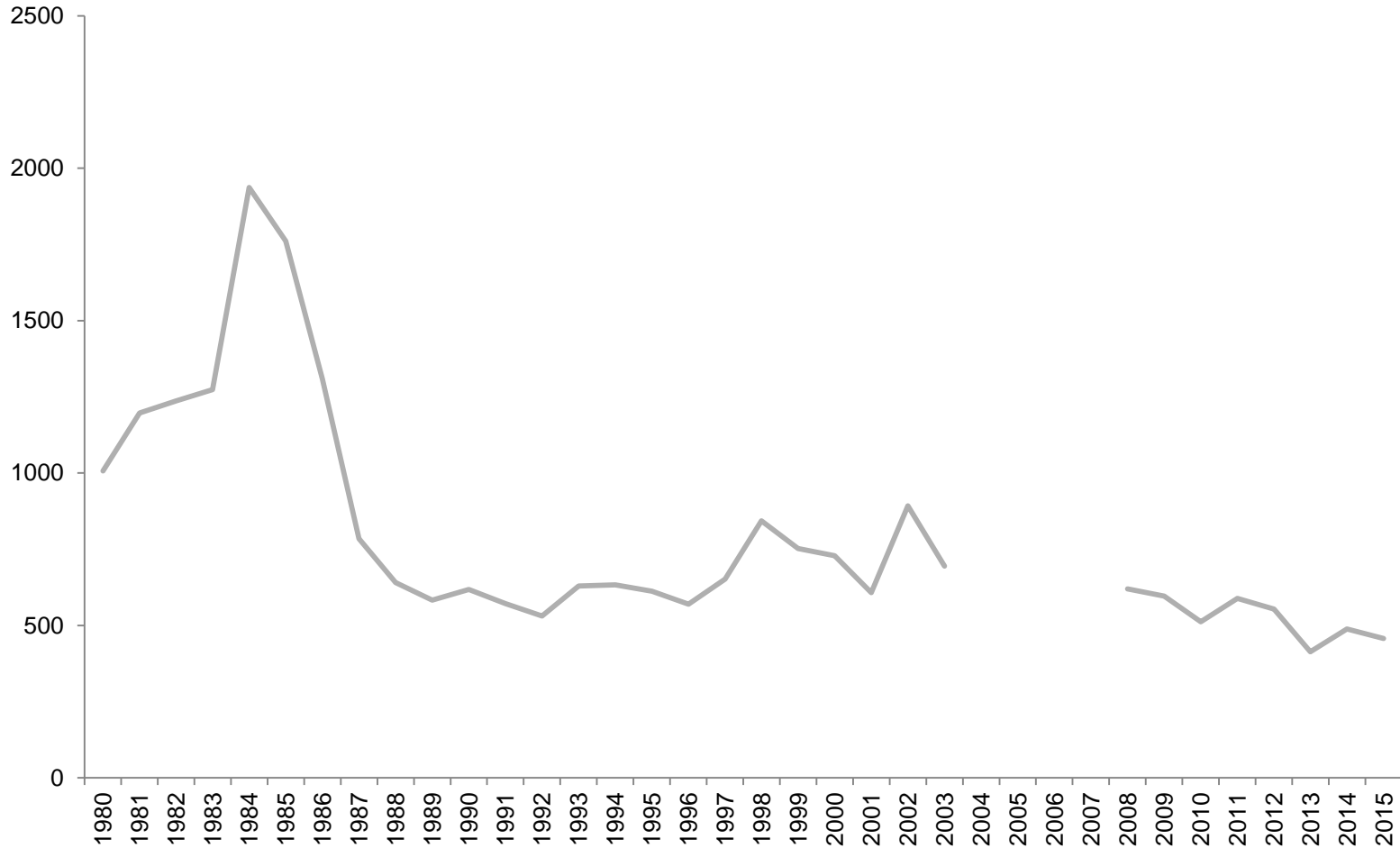
- No specific treatment is available for acute hepatitis B
- Supportive treatment may be indicated for severe clinical manifestations e.g. replacement of fluids lost from vomiting and diarrhoea
- Chronic hepatitis B infection can be treated with oral antivirals which can slow the progression of cirrhosis, reduce incidence of liver cancer and improve long term survival
- Hepatitis B vaccination is the most effective prevention
- A completed course of vaccine induces protective antibody levels in more than 95% of infants, children and young adults
- Protection lasts at least 20 to 30 years
- The vaccine has an excellent record of safety and effectiveness
- As of 2008, 177 countries had incorporated hepatitis B vaccine in their national infant immunisation programmes

# UK hepatitis B epidemiology

- UK is a very low-prevalence country for HepB:  
0.3 - 0.4% UK population infected
- Prevalence of HepB infection varies across the country  
e.g. prevalence rates in antenatal women vary from 0.05 to 0.08% in some rural areas but rise to 1% or more in certain inner city areas
- Higher prevalence in those born in high-endemicity countries, many of whom will have acquired infection at birth or in early childhood
- Incidence of acute infection is low but is higher among those with certain behavioural or occupational risk factors

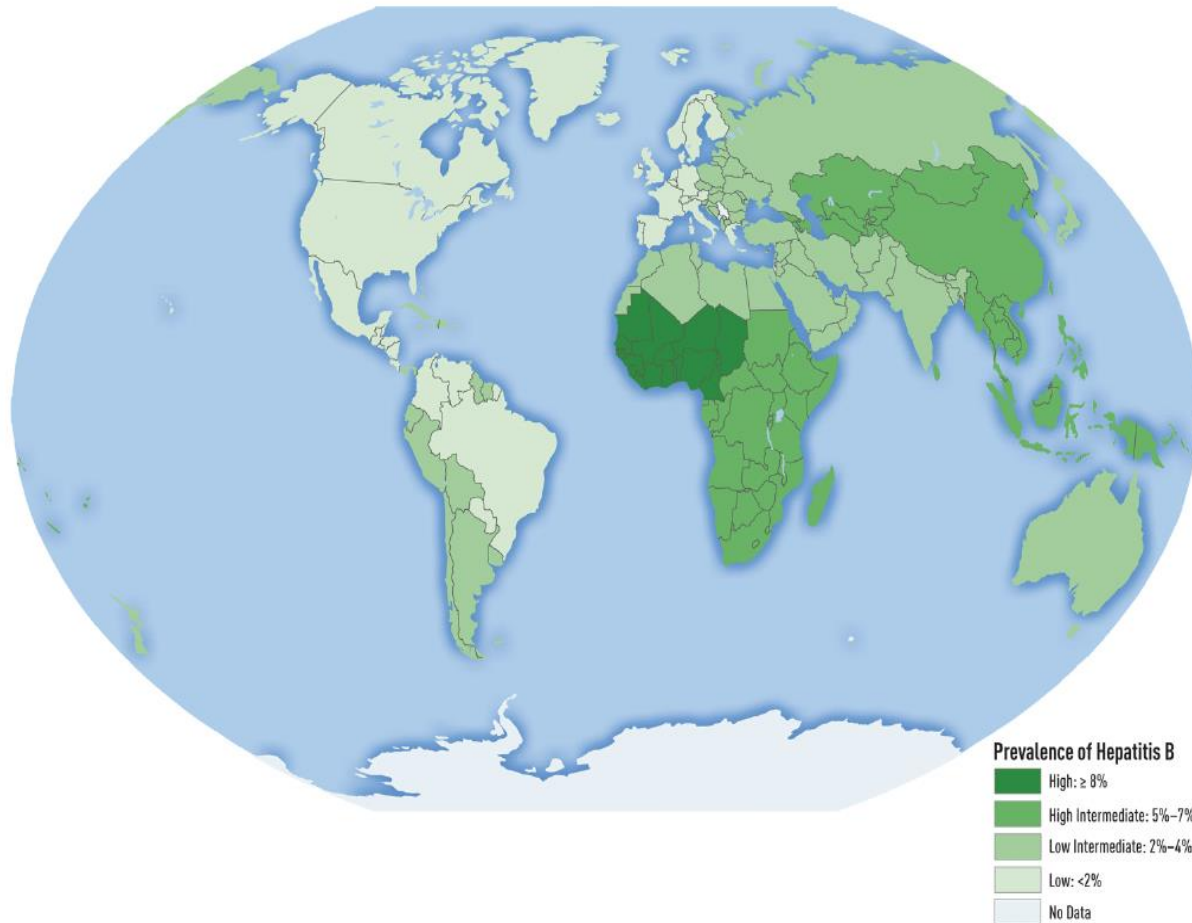
# Laboratory reports of confirmed acute hepatitis B

## England and Wales



From 2008 cases reported on HPZone and matched to laboratory data for England only.  
No data between 2004-2007 due to inability to distinguish between acute and chronic cases

# Global prevalence of chronic hepatitis B (adults)



Source: CDC Health  
Information for  
International Travel  
2016

Globally, hepatitis B is one of the most common infectious diseases  
WHO estimates around 250 million people worldwide are chronically infected



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# The Infanrix hexa® vaccine programme

# The recommended vaccine

- Brand name: Infanrix hexa®
- Multi-component **inactivated** vaccine marketed by GlaxoSmithKline
- Licensed for use from six weeks of age
- Routinely recommended for infants as part of the primary immunisation schedule at 8,12 and 16 weeks
- Infanrix hexa® can also be used for catch-up immunisation for children up to their 10th birthday where these children have missed out on doses of primary immunisations





# Who is eligible to receive Infanrix hexa® vaccine?

- All babies born **on or after** 1<sup>st</sup> August 2017 will become eligible for the vaccine eight weeks after their birth
- Infanrix hexa® vaccine is expected to be made available to order online through the ImmForm website ([www.immform.dh.gov.uk](http://www.immform.dh.gov.uk)) from 1<sup>st</sup> September 2017
- Movianto UK will distribute Infanrix hexa® for use in the routine childhood primary immunisation schedule
- Infants born **before** 1<sup>st</sup> August 2017 should complete the course with pentavalent vaccine (Pediace® or Infanrix-IPV+Hib®)
- Infanrix hexa® should only be given to babies born before 1<sup>st</sup> August if there is no locally held vaccine stock and no further Pediace® or Infanrix-IPV+Hib® can be ordered through ImmForm or if pentavalent vaccine is not readily available

# Is Infanrix hexa® a new vaccine?

- Infanrix hexa® is not a new vaccine
- First licensed for use in Europe in October 2000
- Licensed for use in 97 other countries including Canada, Australia and New Zealand
- Approximately 150 million doses have been given to infants in Europe and across the world
- Infanrix hexa® protects against the same five diseases (tetanus, diphtheria, whooping cough, polio and Hib) as the '5 in 1' vaccines Infanrix®-IPV+Hib and Pediacel®
- The main difference is that Infanrix hexa® also offers protection against hepatitis B

# Is Infanrix hexa® vaccine safe and effective?

- The safety profile of Infanrix hexa® is excellent
- Any adverse events experienced are mild to moderate
  - Same as those experienced following administration of the Pediacel® and Infanrix®-IPV+Hib vaccines
  - Include redness, swelling and tenderness at the injection site, fever, irritability, loss of appetite, diarrhoea and vomiting
- Multiple studies have shown Infanrix hexa® to be safe and highly immunogenic for all its component toxoids/antigens

Dhillon S. DTPa-HBV-IPV/Hib vaccine (Infanrix hexa™) A Review of its Use as a Primary and Booster Vaccination. Drugs 2010; 70(8): 1021-1058 Available at: <https://www.ncbi.nlm.nih.gov/pubmed/20481658>

# Vaccine scheduling

- The infant immunisation schedule remains unchanged at eight, twelve and sixteen weeks of age
- First dose of Infanrix hexa® can be given from six weeks (if required in exceptional circumstances e.g. travel to an endemic country) but not before
- The minimum interval between doses of Infanrix hexa® is four weeks
- Infanrix hexa® can be administered at the same time as, or at any time before or after, any other vaccine
- If primary course is interrupted, resume but don't repeat, allowing an interval of four weeks between the remaining doses
- As with the pentavalent vaccines, Infanrix hexa® should be given to premature infants at the appropriate chronological age, according to the schedule
- Booster doses of hepatitis B will not usually be required for children vaccinated according to the routine childhood schedule

# Contraindications

Infanrix hexa® should not be administered to those who have had:

1. A confirmed anaphylactic reaction to a previous dose of the vaccine OR
2. A confirmed anaphylactic reaction to any component of the vaccine (this includes formaldehyde, neomycin and polymyxin)

There are very few individuals who cannot receive the Infanrix hexa® vaccine

Where there is doubt, instead of withholding immunisation, appropriate advice should be sought from a member of the local Screening and Immunisation or Health Protection team

# Precautions (1)

- As for pentavalent vaccine, there are very few occasions when deferral of immunisation with Infanrix hexa® is required
- If infant has a minor illness without fever or systemic upset, immunisations can still be given
- If infant is acutely unwell (e.g. fever above 38.5°C), immunisation may be postponed until they have fully recovered
- This is to avoid wrongly attributing any new symptom or the progression of symptoms to the vaccine
- The presence of a neurological condition is not a contraindication to immunisation but if evidence of current neurological deterioration, deferral of DTaP/IPV/Hib/HepB vaccination may be considered to avoid incorrect attribution of any change in the underlying condition
- Risk of deferral should be balanced against risk of infection and vaccination should be given promptly once diagnosis and/or expected course of the condition becomes clear

# Precautions (2)

## Premature infants

- Very premature infants (born  $\leq 28$  weeks of gestation) who are in hospital should have respiratory monitoring for 48-72 hrs when given their first immunisation, particularly those with a previous history of respiratory immaturity
- If the premature infant has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hrs

# Systemic and local reactions following a previous immunisation

Children who have had a systemic or local reaction following a previous immunisation with DTaP/IPV/Hib/HepB or DTaP/IPV/Hib including:

- fever, irrespective of its severity
- hypotonic-hyporesponsive episodes (HHE)
- persistent crying or screaming for more than three hours, or
- severe local reaction, irrespective of extent

can continue to receive subsequent doses of DTaP/IPV/Hib/HepB vaccine



# Infanrix hexa® vaccine composition

## After reconstitution, 1 dose (0.5 ml) contains:

- Diphtheria toxoid
- Tetanus toxoid
- *Bordetella pertussis* antigens
  - Pertussis toxoid (PT)
  - Filamentous Haemagglutinin (FHA)
  - Pertactin (PRN)
- Hepatitis B surface antigen (HBs)
- Poliovirus (inactivated) (IPV)
  - type 1 (Mahoney strain)
  - type 2 (MEF-1 strain)
  - type 3 (Saukett strain)
- *Haemophilus influenzae* type b polysaccharide (polyribosylribitol phosphate, PRP)
  - conjugated to tetanus toxoid as carrier protein

## Adjuvants:

- Aluminium hydroxide, hydrated ( $\text{Al}(\text{OH})_3$ )
- Aluminium phosphate ( $\text{AlPO}_4$ )

## Excipients:

- Lactose anhydrous
- Sodium chloride ( $\text{NaCl}$ )
- Medium 199 containing principally amino acids, mineral salts, vitamins
- Water for injections

The vaccine may contain traces of formaldehyde, neomycin and polymyxin which are used during the manufacturing process

Infanrix hexa® does not contain any porcine gelatine or thiomersal

# How is Infanrix hexa® vaccine presented?

- The DTaP/IPV/HepB component is presented as a cloudy white suspension in a pre-filled glass syringe. Upon storage, a clear liquid and a white deposit may be observed
- The lyophilised (freeze dried) Hib vaccine is presented as a white powder in a glass vial
- The vaccine is supplied in single dose packs containing the syringe, vial and two needles:
  - Green needle for reconstitution
  - Blue needle for vaccine administration



# What are the steps involved in preparing Infanrix hexa®?

1. Shake the pre-filled syringe containing the DTaP/IPV/HepB suspension to obtain a consistent, cloudy, white suspension
2. Attach the green needle supplied to the pre-filled syringe of DTaP/IPV/HepB and inject the entire contents of the syringe into the vial containing the Hib vaccine
3. Shake the vial vigorously until the powder has completely dissolved
4. Withdraw the entire mixture back into the syringe
5. Inspect the vaccine suspension for any foreign particulate matter and/or abnormal physical appearance. If either is observed, discard the vaccine
6. Replace the green needle with the blue needle supplied and administer the vaccine intramuscularly

**\*DO NOT FORGET TO RECONSTITUTE THE HIB COMPONENT\***

# Storage and administration

- Infanrix hexa® should be stored between +2°C to +8°C
- It must be stored in its original packaging to:
  - protect it from light
  - ensure the component parts are kept together
  - retain the batch number and expiry date for the entire product which is printed on the outer vaccine carton
- Infanrix hexa® should be administered intramuscularly
- Infants with a bleeding disorder should receive the vaccine by deep subcutaneous injection to reduce the risk of bleeding
- Preferred site of injection for infants under one year of age is the anterolateral aspect of the thigh
- It can be given in the same thigh as the PCV vaccine at the 8 and 16 week immunisation appointments (minimum of 2.5cm apart)

# Post-immunisation care recommendations

- The recommendations following administration of Infanrix hexa® vaccine are the same as with the administration of Pediacel® and Infanrix®-IPV+Hib vaccines
- When PCV is given alongside infant DTaP-containing combination vaccines, the rate of fever is higher than when either vaccine is administered alone
- In the current UK schedule, infants receive these vaccines alongside MenB vaccination at 8 and 16 weeks of age
- The routine recommendation to offer prophylactic paracetamol with the infant doses of MenB is expected to also reduce the rate of fever attributed to co-administration of PCV
- Please see MenB vaccine and paracetamol information and “What to expect after vaccinations” leaflet on the PHE Immunisation webpage for more information

**NHS**

## Using paracetamol

to prevent and treat fever after MenB vaccination

**My baby has just had the MenB vaccine, what should I expect?**  
Fever can be expected after any vaccination, but it is more common when the MenB vaccine (Bexsero) is given with the other routine vaccines at two and four months. Without paracetamol, more than half of infants will develop a temperature after these vaccines. The fever tends to peak about 6 hours after vaccination and is usually less than 39°C (102.2°F) within two days. The fever shows the baby's immune system is responding to the vaccine, although the level of fever will depend on each child and does not show how well the vaccine will protect your baby.

**How can I reduce the risk of fever?**  
Giving paracetamol soon after vaccination – and not waiting for a fever to develop – will reduce the risk of your child having a fever with paracetamol, fewer than one in five children will get a fever and nearly all of these are mild (below 39°C). The paracetamol will also reduce the chance of your baby being irritable or suffering discomfort such as pain at the site of the injection.

**Which paracetamol product should I use?**  
You should use an infant paracetamol suspension. This kind of paracetamol comes in liquid form for use in babies and young children. It has a strength of 120mg/5ml.

**If you have not already got some paracetamol suspension for infants at home, you should get some from your local pharmacy or supermarket so that you can give the first dose of paracetamol within an hour of the vaccination. There are various products to choose from (including bottles and sachets) but the type needed is infant paracetamol suspension 120mg/5ml.**

**After which vaccinations should I give my baby paracetamol?**  
Paracetamol is advised for your baby following the MenB vaccination. The MenB vaccine is usually given at your baby's first and third immunisation appointments at two months and four months of age.

**Paracetamol is not routinely needed after the MenB booster vaccine given at 12 months of age. By this age the baby's risk of fever is the same as after other vaccines.**

**How much paracetamol should I give?**  
A total of three doses of 2.5ml (50mg) of paracetamol are recommended following MenB vaccination. You should give the first dose at the time of vaccination or as soon as possible afterwards. You should then give the second dose of paracetamol around four to six hours after the first dose. You should then give a third dose four to six hours after the second dose. The 2.5ml dose should be measured and given either using a syringe or with a 2.5ml spoon (this is usually the end of the spoon that comes in the pack).

**For any temperature below 38°C before 12 weeks gestation, paracetamol should be prescribed by your doctor according to the instructions on the pack. You should check with your doctor and follow the instructions on the prescription.**

**Dosage and timing of infant paracetamol suspension (120mg/5ml) for use after primary MenB vaccination (usually at two and four months of age)**

Age of baby	Up to 6 months (usually at 2 and 4 months)
Dose 1	One 2.5ml (50mg) dose as soon as possible after vaccination
Dose 2	One 2.5ml (50mg) dose 4-6 hours after first dose
Dose 3	One 2.5ml (50mg) dose 4-6 hours after second dose

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**NHS**

## What to expect after vaccinations

This leaflet tells you about the common side effects of vaccinations that might occur in babies and young children up to five years of age.

**After a vaccination, your baby may cry for a little while, but that usually settles soon with a cuddle or a feed. Most babies don't have any other reaction.**

**Reactions at the site of the injection**  
Some babies have some swelling, redness or a small hard lump where the injection was given and it may be sore to touch. This usually only lasts two to three days and doesn't need any treatment.

**Fever**  
A fever is a temperature over 37.5°C. Fevers are quite common in young children, but are usually mild. If your child's face feels hot to the touch and they look red or flushed, he or she may have a fever. You can check their temperature with a thermometer.

**If your baby has a fever:**  
• make sure they don't have too much clothing or bedding on them, and  
• give them plenty of cool fluids.  
• do not put them in a bath, sponge them down or put a fan on them

**After vaccination with MenB**  
Fever can be expected after any vaccination, but is very common when the MenB vaccine is given with the other routine vaccines at two and four months. The fever shows the baby's body is responding to the vaccine, although not getting a fever doesn't mean it hasn't worked. The level of fever depends on the individual child and does not indicate how well the vaccine has worked. Giving paracetamol will reduce the risk of fever, irritability and general discomfort (including pain at the site of the injection) after vaccination.

**After each of the two-month and four-month vaccinations you will need to give your baby a total of three doses of paracetamol (2.5ml of infant paracetamol 120mg/5ml suspension) to prevent and treat any potential fever. You should give the first dose of paracetamol as soon as possible after your two-month vaccination visit. You should then give the second dose four to six hours later and the third dose four to six hours after that. You will need to follow the same steps after**

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# Administration of Infanrix hexa®

**Infanrix hexa® should only be supplied and administered:**

- Against a prescription written manually or electronically by a registered medical practitioner or other authorised prescriber
- Against a Patient Specific Direction
- Against a Patient Group Direction

A patient group direction (PGD) template for Infanrix hexa® will be available on the PHE website <https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd>

Those using national immunisation PGDs developed by PHE must ensure that each PGD is organisationally authorised and signed in section 2 by an appropriate authorising person, in accordance with Human Medicines Regulations 2012 (HMR2012)

Without such authorisation, the PGD is not legal or valid

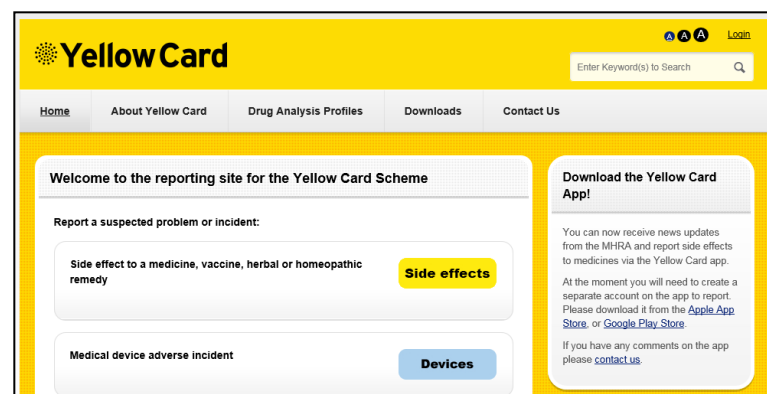
# Possible adverse reactions

**Most commonly** reported (seen in more than 1 in 10 doses of the vaccine)

- Loss of appetite, fever ( $>38^{\circ}\text{C}$ ), abnormal crying, irritability and restlessness
- Local swelling, pain and redness at the injection site

Hypersensitivity reactions, such as angioedema, urticaria and anaphylaxis can occur but are rare, as can convulsions (with or without fever) and hypotonic-hyporesponsive episodes (also rare)

Suspected adverse reactions should be reported to the MHRA using the Yellow Card reporting scheme at:  
<https://yellowcard.mhra.gov.uk/>



# Routine monitoring of vaccine coverage

- Hexavalent vaccine coverage will be monitored routinely through the COVER programme alongside all other childhood immunisations
- COVER data are extracted from Child Health Information Systems (CHIS) at the local authority level and published quarterly as official statistics

## Routine childhood programme

### COVER data:

- Percentage of eligible children in the local authority who have completed a primary course (3 doses), anytime up to the 1<sup>st</sup>, 2<sup>nd</sup> and 5<sup>th</sup> birthday

## Selective 'at-risk' infants

### programme COVER data:

- Percentage of eligible children in the local authority who have received 5 doses of HepB-containing vaccine\* anytime up to the 1<sup>st</sup> birthday
- Percentage of eligible children in the local authority who have received 6 doses of HepB-containing vaccine\*\* anytime up to the 2<sup>nd</sup> birthday

\*two monovalent and three Infanrix hexa®

\*\*three monovalent and three Infanrix hexa®



# Local monitoring of vaccine coverage data

- Hexavalent and monovalent HepB vaccine coverage will also be monitored via ImmForm
- Aggregated GP-level data will be extracted to monitor dose specific coverage at an earlier age than the routine COVER programme
- These data are for local performance management purposes only and will not be published

## Routine childhood programme ImmForm GP data :

- Hexavalent vaccine coverage for 1, 2 and 3 doses evaluated at 6 months of age

(percentage of eligible individuals who have received 0, at least 1, at least 2 and 3 doses of hexavalent vaccine)

## Selective 'at-risk' infants programme ImmForm GP data :

- HepB vaccine coverage for 1, 2 and 3 doses at 3 months of age

(percentage of eligible individuals who have received 0, at least 1, at least 2 and 3 doses of HepB-containing vaccine)

AND

- percentage who were tested for HBsAg at 18 months



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# Neonatal selective immunisation programme for babies at risk of hepatitis B

# Implications for babies at high risk of hepatitis B infection

- Babies born to mothers chronically infected with HBV or who have had acute hepatitis B during pregnancy are at risk of becoming infected with HBV
- Objective of the selective neonatal hepatitis B immunisation programme is to provide post exposure immunisation to infants born to HBV infected mothers to prevent mother to child transmission at or around the time of birth
- With the introduction of hepatitis B vaccine into the routine schedule:
  - the maternal hepatitis B screening programme will continue as it remains essential to identify unborn babies at risk of infection
  - the neonatal selective immunisation programme will continue so that high risk infants receive a dose of HepB vaccine at birth followed by a dose at four weeks of age

# Why is the selective neonatal immunisation programme continuing if all infants will receive hepatitis B vaccine?

- HBV infection can be transmitted from infected mothers to their babies at or around the time of birth as infected blood from the mother passes through placenta to baby during delivery
- Babies acquiring infection at this time have a high risk of becoming chronically infected with the virus
- Over 90% of chronic infection in infants born to infected mothers after perinatal transmission can be prevented by appropriate post-exposure prophylactic vaccination starting at birth
- Timely vaccination at birth and at one month of age is critical to preventing infant infection
- The dose that is given to all babies at eight weeks of age (as part of the universal programme) would be too late to prevent infection in those high risk babies who are exposed at or around birth

# Hepatitis B vaccine schedule for routine and at risk infant immunisation programmes

Age	Routine childhood		Babies born to hepatitis B infected mothers	
Birth	X*		✓	<b>Monovalent HepB</b> (Engerix B or HBvaxPRO Paediatric) (with HBIG if indicated)
4 weeks	X		✓	<b>Monovalent HepB</b> (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	X		✓	<b>Monovalent HepB</b> (Engerix B or HBvaxPRO Paediatric) <u>Test for HBsAg</u>

\*Babies born to hepB negative mothers but going home to a household with another hepatitis B infected person may be at immediate risk of hepatitis B infection so should be given a monovalent dose of hepatitis B vaccine before discharge from hospital

# Blood tests for high risk infants

- Although hepatitis B vaccine is highly effective at preventing infection if given at birth, a very small number of infants may still acquire infection despite vaccination and immunoglobulin
- Testing high risk infants at 12 months of age is important to enable timely assessment of their infection status
- Finding out if infant is infected at this point can reduce risk of long term complications and disease in later life
- The purpose of the 12 month blood test is to check for infection, not to check or measure response to the vaccine
- Numerous studies have already demonstrated that infants make a protective response to a course of hepatitis B given in the first year of life
- More information on blood testing available at:  
<https://www.gov.uk/guidance/hepatitis-b-dried-blood-spot-dbs-testing-for-infants>

# Booster doses for high risk infants

## 12 month hepatitis B booster:

- A further dose of monovalent HepB vaccine should be given at one year of age, alongside a test for hepatitis B surface antigen (HBsAg)
- Testing at one year of age important to identify babies who have become chronically infected with hepatitis B despite vaccination

## Pre-school hepatitis B booster:

- Increasing evidence that protection is long-lasting and benefits of booster doses therefore limited
- 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 hexavalent DTaP/IPV/Hib/HepB vaccine
- Pre-school booster vaccine appointment provides an opportunity to check child has been appropriately managed, i.e. fully immunised against hepatitis B and tested for infection



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# Sources of information



# Healthcare practitioner questions

Further information and commonly asked questions about the inclusion of hepatitis B containing vaccine in the routine and selective infant immunisation schedule are available in the following documents:

- **The hexavalent DTaP/IPV/Hib/HepB combination vaccine:**

Information for healthcare practitioners about the inclusion of hepatitis B vaccine in the routine infant immunisation programme

- **The hexavalent DTaP/IPV/Hib/HepB combination vaccine**

Information for healthcare practitioners about the neonatal selective immunisation programme for babies at risk of hepatitis B

Available on PHE Immunisation webpage  
<https://www.gov.uk/government/collections/immunisation>

# Further sources of information

- Public Health England. Immunisation against infectious disease (The Green Book) Hepatitis B chapter 18. Available at:  
<https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18>
- Public Health England. Immunisation page contains information for healthcare professionals, parent/carer information, PGD for the hexavalent vaccine <https://www.gov.uk/government/collections/immunisation>
- European Medicines Agency. Summary of the European public assessment report for Infanrix hexa®. Available at:  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000296/human\\_med\\_000833.jsp&mid=WC0b01ac058001d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000296/human_med_000833.jsp&mid=WC0b01ac058001d124)
- Infanrix hexa® Summary of Product Characteristics. Available at:  
<https://www.medicines.org.uk/emc/medicine/33313>

# Key points

- Babies born on or after 1<sup>st</sup> August 2017 will be offered a hexavalent DTaP/IPV/Hib/HepB vaccine (Infanrix hexa®) which will protect against hepatitis B
- Hepatitis B is a viral infection that attacks the liver and can cause hepatic necrosis, cirrhosis and an increased risk of developing liver cancer
- Infanrix hexa® is licensed for use in 97 countries and approximately 150 million doses have been given to infants worldwide
- Multiple studies have shown Infanrix hexa® to be safe and highly immunogenic
- Any adverse events experienced are mild to moderate and the same as those following administration of the pentavalent vaccines (Pediace® and Infanrix®-IPV+Hib)
- The infant immunisation schedule remains unchanged at 8,12 and16 weeks