Childhood Immunisation Update Training

Aug 2017



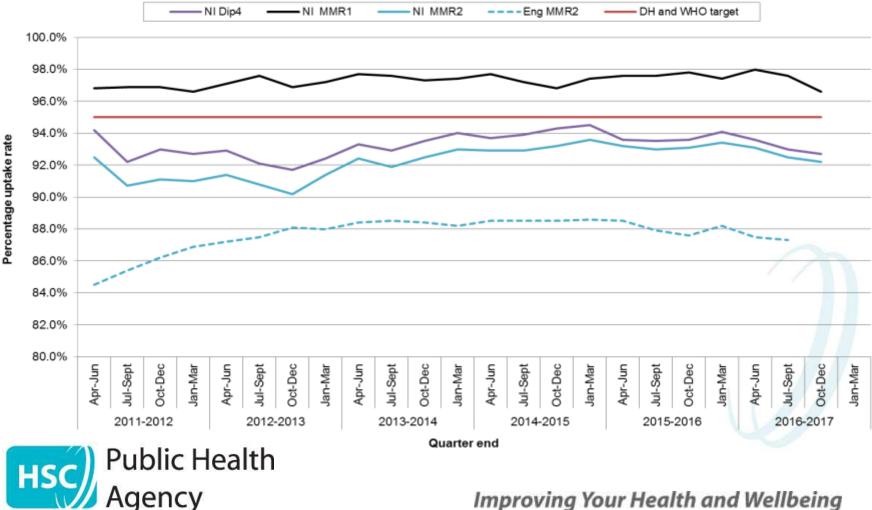
What we will cover

- Improving uptake and the CHS system
- Rotavirus vaccine
- Men ACWY current programme
- The new hexavalent vaccine introduction



NI imms update good, but decreasing

Diphtheria and MMR vaccination uptake rates at 5 years, Northern Ireland and England, April 2011 - December 2016



Child Health Information System

Vital resource to assist with call-recall system for imms appointments

BUT:

It is only a computer

Only as good as the information that practices feed into it



How to get the best out of CHS

Record correctly whether a DNA is a 2 (didn't attend- reason given) or 3 (didn't attend- no reason)

If someone is a 2 or 3 twice, make contact with them to explore why they haven't come. Repeated appointments unlikely to help

Check address of child CHS have is correct

Send lists back to CHS at the end of each clinic- V. short turn around to send the 2,3, 4 month appointments out



Public Health

Waiting lists/Queues

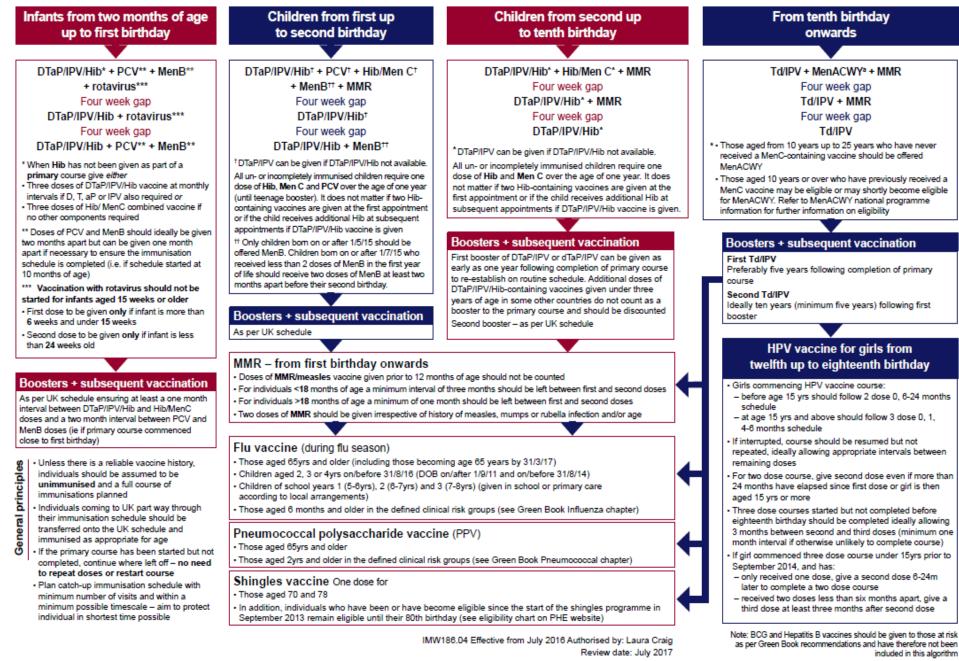
- These are children due to be immunised but no slots are available at the practice to put them into.
- List length and names of children sent on clinic lists
- Practice should review slots available and ensure there are enough for registered children
- Check waiting list- is address correct, have they received immunisation- inform CHIS of updates
- Then CHIS can schedule one off clinics to catch-up on children waiting.



総 Public Health England

Vaccination of individuals with uncertain or incomplete immunisation status

For online Green Book, see www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book • For other countries' schedules, see http://apps.who.int/immunization_monitoring/globalsummary/



Rotavirus vaccine





Vaccination against rotavirus – use of Rotarix®

- Prefilled oral tube
- > Oral suspension
- Each dose contains
- 1.5ml of clear
 colourless liquid
 Changing to this in Oct





Vaccination against rotavirus – Rotarix® dosage and schedule

- 2 dose schedule
- First dose of 1.5ml at 8 weeks (two months) of age
- Second dose of 1.5ml at least four weeks after the first (i.e. 12 week appointment)

- If interrupted resume course and no need to repeat first dose



Vaccination against rotavirus – Rotarix® dosage and schedule

Both doses ideally by 15 weeks (i.e.14 weeks and 6 days) and no later than 24 weeks of age (i.e. 23 weeks and 6 days)

- The first dose must be given before 15 weeks of age. If infant does not have first dose before 15 weeks then do not give Rotarix®
- If infant spits out/regurgitates most of dose, one replacement dose may be given at same visit



Men ACWY





Current Men ACWY Programme

School nurses will still offer Men ACWY to year 11's with further offer in yr 12.

Still in GP contract that anyone with DOB 2/7/96-1/7/01 may REQUEST vaccine from GP and GP will be paid to give it.

First time uni students up to age 25 year who have not had a dose of conjugated Men ACWY vaccine over age 10 yrs can also request from GP.



Routine childhood immunisations from October 2017

| When to immunise | Diseases protected against | | Vaccine given | Immunisation site* |
|--|---|--|--|----------------------------|
| Two months old | Diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type b (Hib) and hepatitis B (6 in 1) | | DTaP/IPV/Hib/HepB (Infanrix hexa)*t | Thigh |
| | Pneumococcal disease | | PCV (Prevenar 13) | Thigh |
| | Rotavirus | | Rotavirus (Rotarix) | By mouth |
| | Meningococcal group B disease (MenB) | | MenB (Bexsero) | Left thigh |
| Three months old | Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (6 in 1) | | DTaP/IPV/Hib/HepB (Infanrix hexa)* | Thigh |
| | Rotavirus | | Rotavirus (Rotarix) | By mouth |
| Four months old | Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (6 in 1) | | DTaP/IPV/Hib/HepB (Infanrix hexa)* | Thigh |
| | Pneumococcal disease | | PCV (Prevenar 13) | Thigh |
| | Meningococcal group B disease (MenB) | | MenB (Bexsero) | Left thigh |
| Between 12 and 13 months old – within a month of the first birth- day | Measles, mumps and rubella (German measles) | | MMR (Priorix or MMR VaxPRO) | Upper arm/thigh |
| | Pneumococcal disease | | PCV (Prevenar 13) | Upper arm/thigh |
| | Hib/MenC | | Hib/MenC (Menitorix) | Upper arm/thigh |
| | Meningococcal group B disease (MenB) | | MenB (Bexsero) | Left thigh |
| Every year from 2 years old up to P7 | Influenza (from September) | | Flu nasal spray (Fluenz Tetra) (annual). (If Fluenz unsuitable, use inactivated flu vaccine) | Nostrils (or upper arm) |
| Three years four months old or soon after | Diphtheria, tetanus, pertussis and polio | | dTaP/IPV (Repevax) or DTaP/IPV (Infanrix IPV) ¹ | Upper arm |
| | Measles, mumps and rubella | | MMR (Priorix or MMR VaxPRO) ¹ (check first dose has been given) | Upper arm |
| Girls aged 12 to 13 years | Cervical cancer caused by human papillomavirus types 16 and 18 (and genital warts caused by types 6 and 11) | | HPV (Gardasil) | Upper arm |
| Around 14 years old | Tetanus, diphtheria and polio | | Td/IPV (Revaxis), and check MMR status | Upper arm |
| | Meningococcal groups ACWY disease (MenACWY) | | MenACWY(Nimenrix or Menveo) | Upper arm |

* Only babies born from 1 August 2017 are eligible to receive Infanrix Hexa. Babies born before this date should complete their immunisation course with Pediacel or Infanrix IPV Hib where this is still available.

New Hexavalent vaccine

- From autumn 2017, <u>all babies born on or after 1 August</u> <u>2017</u> 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?

- Since 1992, the World Health Assembly has recommended every country should have a universal hepatitis B immunisation programme
- However, as UK 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.
- The virus is transmitted through contact with the blood or other body fluids of an infected person.
- Two billion people worldwide have been infected with the virus, more than 240 million have chronic (long-term) liver infections, and about 600 000 people die every year due to the consequences of hepatitis B.
- The hepatitis B virus is 50 to 100 times more infectious than HIV.
- Hepatitis B is an important occupational hazard for health workers.
- Hepatitis B is preventable with the currently available safe and effective vaccine



Global prevalence of chronic hepatitis B

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

chronically infected Public Health Agency Prevalence of Hepatitis B High: 2 8% High Intermediate: 5%-7% Low Intermediate: 2%-4% Low: <2% No Data

Modes of transmission

- The virus is transmitted by exposure to infected blood or body fluids
- Transmission most commonly occurs:
- Perinatal transmission: mother to child
- Early childhood
- Parenteral transmission: exposure to blood/other infective fluids
- Sexual transmission: unprotected contact with an infected person



Hepatitis B Infection

Acute infection:

•Many new infections are subclinical or have flu like illness

•Anorexia, nausea, ache in the right upper abdomen, mild fever, malaise, disinclination to smoke or drink

- •Jaundice occurs in 10% of younger children and 30-50% of adults
- Chronic HBV infection develops in 90% of those infected as infants and approx 10% infected as adults
- 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



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Treatment and prevention

- No specific treatment is available for acute hepatitis B
- Supportive treatment may be indicated for people with severe clinical manifestations e.g. replacement of fluids lost from vomiting and diarrhoea.
- Chronic hepatitis B infection can be treated but not cleared with oral antivirals which can slow the progression of cirrhosis, reduce incidence of liver cancer and improve long term survival
- The hepatitis B vaccine 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 including Ireland



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 higher among those with certain behavioural or occupational risk factors

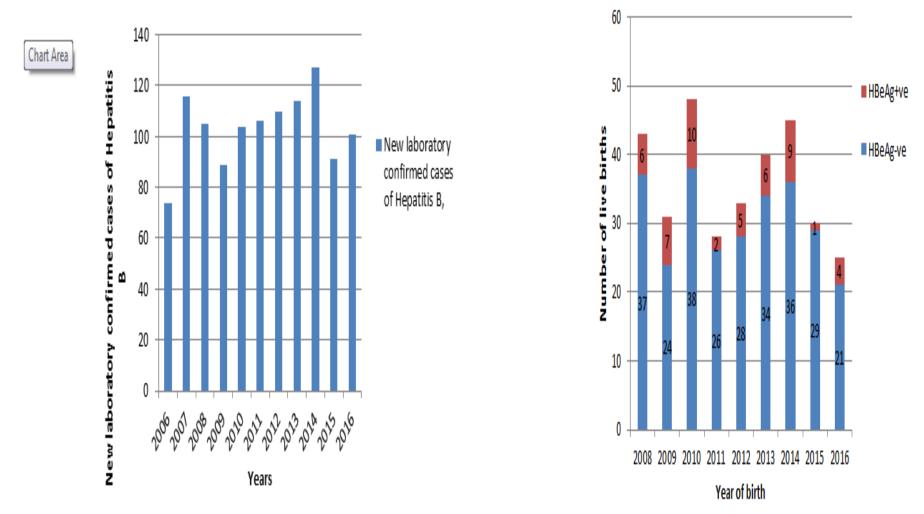


Public Health Agency

Northern Ireland data

Figure 1: New Laboratory-confirmed cases of hepatitis B in Northern Ireland, 2006–2016

Figure 4: Number of live births to Hepatitis B positive Mothers (DOB 2008 - 2016), Northern Irel



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 1st August 2017 will become eligible for the vaccine eight weeks after their birth
- Infanrix hexa® vaccine is expected to be made available to order from September 2017
- Infants born before 1st August 2017 should complete the course with pentavalent vaccine (Pediacel® or Infanrix-IPV+Hib®).
- Infanrix hexa® should only be given to babies born before 1st August if there is no locally held vaccine stock and no further Pediacel® or Infanrix-IPV+Hib® can be ordered



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 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: <u>https://www.ncbi.nlm.nih.gov/pubmed/20481658</u>



Vaccine scheduling

- The infant immunisation schedule remains unchanged at eight, twelve and sixteen weeks of age
- The 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 subsequent 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 the primary course is interrupted it should be resumed but not repeated, allowing an interval of one month 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 will not usually be required for children vaccinated according to the routine childhood schedule



Contraindications

- 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 consultant with immunisation expertise or from the PHA duty room
- Infanrix hexa® should not be administered to those who have had:
- A confirmed anaphylaxis to a previous dose of the vaccine OR
- 2. A confirmed anaphylaxis to any constituent or excipient of the vaccine (this includes formaldehyde, neomycin and polymyxin).



Precautions

- 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 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 deferral should be balanced against the risk of the infection and vaccination should be given promptly once the diagnosis and/or the expected course of the condition becomes clear.



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Precautions (2)

Premature infants

- Very premature infants (born ≤ 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



- Aluminium hydroxide, hydrated (Al(OH)3)
- Aluminium phosphate (AIPO4)

Excipients:

- Lactose anhydrous13
- Sodium chloride (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 for reconstitution and Blue one for vaccine administration





What are the steps involved in preparing Infanrix hexa®?

- Shake the pre-filled syringe containing the DTaP/IPV/HepB suspension in order to obtain a consistent, cloudy, white suspension
- Attach the green needle to the pre-filled syringe of DTaP/IPV/HepB and inject the entire contents of the syringe into the Hib vial
- 3. Shake the Hib vial vigorously until the powder has completely dissolved
- 4. Withdraw the entire mixture back into the syringe

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- 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 for injection and administer the vaccine intramuscularly

DO NOT FORGET TO RECONSTITUTE THE HIB Public Health 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 week 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 infant DTaP-containing combination vaccines are given alongside other infant vaccines such as PCV and MenB, an increased risk of febrile reactions and other related side effects is seen
- It is therefore recommended that <u>paracetamol</u> is given when the MenB vaccine is administered with PCV and the hexavalent vaccine at 8 weeks and 16 weeks of age Public Health

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) for Infanrix hexa® will be available



Possible adverse reactions

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

- Loss of appetite, fever (>38°C), fatigue (tiredness), abnormal crying, irritability and restlessness
- Local swelling, pain and redness at the injection site

Suspected adverse reactions should be reported to the MHRA using the yellow card scheme <u>http://mhra.gov.uk/yellowcard</u>



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 who are chronically infected with hepatitis B virus (HBV) or to mothers who have had acute hepatitis B during pregnancy are at risk of becoming infected with HBV
- The objective of the selective neonatal hepatitis B immunisation programme is to provide post exposure immunisation to infants born to hepatitis B 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 selective neonatal immunisation programme will continue so that high risk infants receive a dose of HepB vaccine at birth followed by a dose one month later



Why is the selective neonatal immunisation programme continuing if all infants are going to receive hepatitis B vaccine?

- Hepatitis B 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 the placenta to the 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 postexposure prophylactic vaccination starting at birth
- Timely vaccination at birth and at one month of age is critical to • preventing infection in the infant
- 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 aencv

What is the vaccine schedule for high risk infants?

| Age | Routine childhood | | Babies born to hepatitis B infected mothers | |
|----------|-------------------|--------------------------------------|---|---|
| Birth | X | | ✓ | Monovalent HepB (Engerix B or HBvaxPRO Paediatric) (with HBIG if indicated) |
| 4 weeks | X | | ~ | 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 | X | | ~ | Monovalent HepB (Engerix B or HBvaxPRO Paediatric) Test for HBsAg |



Blood tests for high risk infants

- Although the hepatitis B vaccine is highly effective at preventing infection if given at birth, a few infants may still acquire infection despite vaccination and immunoglobulin
- Testing high risk infants at 12 months of age is important to enable a timely assessment of their infection status
- Finding out if the infant is infected at this point can reduce the 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



Booster doses for high risk infants

12 month hepatitis B booster:

- A Further dose of monovalent hep B vaccine should be given at 1 year of age, before the test for HBsAg
- Testing at 1 year of age is to identify those who have become 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



Further sources of information

- Public Health England. Immunisation against infectious disease (The Green Book) Diphtheria, Tetanus, Pertussis, Polio, Hib and Hepatitis B chapters. Available at: <u>https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</u>
- 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
- Infanrix hexa® Summary of Product Characteristics. Last updated March 2017. Available at: <u>http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-</u> <u>Product_Information/human/000296/WC500032505.pdf</u>

http://pha.site/immunisationvaccine-preventable-diseases- PHA immunisation page contains updated leaflets for parents including translations and an FAQ document for health professionals with more details on the programme.



Key points

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- Babies born on or after 1st 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 hepatocellular carcinoma
- 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 are the same as those experienced following administration of the pentavalent vaccines (Pediacel® and Infanrix®-IPV+Hib)
- The infant immunisation schedule remains unchanged (at 8,12,16
 weeks)

Questions?

A presentation on updates for the flu immunisation programme for 2017 is also available on the PHA website.

Please see <u>http://pha.site/immunisationvaccine-</u> preventable-diseases- for all current health professional and patient information

If you have questions about details in this presentation, or other non-urgent immunisation queries e.g. about leaflets or vaccine ordering, please email them to: pha.immunisation@hscni.net

