# INFANT IMMUNISATION GUIDELINES

Poole Hospital NHS
NHS Foundation Trust

For all immunisations it is imperative that ***parental consent*** is obtained prior to proceeding. Use the 'Immunisation Consent and Administration Form'. Once administered, fax completed form to the Child Health Information Service to inform them of any immunisations given in hospital and ensure that the infant can be called at the correct time for future doses in community.

## IMMUNISATION OF INFANTS WITH HIV-POSITIVE MOTHERS

Infants born to HIV-positive mothers should follow the routine national primary immunisation schedule (BHIVA).

Generally, **BCG vaccine** should only be given when the exclusively formula-fed infant is confirmed HIV uninfected at 12–14 weeks. However, infants considered at low risk of HIV transmission (maternal VL <50 HIV RNA copies/mL at or after 36 weeks' gestation) but with a high risk of tuberculosis exposure may be given BCG at birth (BHIVA).

Where the mother is co-infected with **Hepatitis B** (HBV), immunization against HBV infection should be as per the Green Book and does not differ from management of the HIV-unexposed infant.

**Rotavirus vaccine** (Rotavirix®) is advised in HIV-infected infants. Additionally infants with unknown HIV status but born to HIV-positive mothers should be offered vaccination (PHE).

**Varicella vaccine** is contraindicated for HIV-infected individuals with severe immunosuppression (defined in Green Book chapter 6 v2, Table 6.1). This guidance may be relaxed in the near future as evidence is emerging that patients with moderate immunosuppression can be safely vaccinated and will make an adequate response. For HIV-infected individuals with no immunosuppression who are susceptible to varicella, vaccine is indicated to reduce the risk of serious chickenpox or zoster should their condition deteriorate.

## IMMUNISATIONS AT BIRTH

### HEPATITIS B VACCINE:

All babies born to mothers with a history of illegal drug use should receive a complete course of hepatitis B vaccination on time, regardless of mum's hepatitis status as they are deemed to have been exposed to a 'high risk' environment.
The vaccination schedule consists of four IM doses of 10mcg (0.5ml) hepatitis B vaccine (Engerix B® brand) at birth, 1, 2 and 12 months into the upper arm or anterolateral thigh (efficacy is reduced if given in the buttock). **Initial dose must be given prior to discharge from hospital**.

At 12 months, it will be necessary to check the baby's hepatitis B antigen status to determine whether the intervention has been successful.

### HEPATITIS B IMMUNOGLOBULIN:

Babies born to highly infectious mothers must also receive hepatitis B immunoglobulin (HBIG) aswell as active immunisation:

| | **Baby should receive:** | |
|---|---|---|
| **Hepatitis B status of mother:** | **Hepatitis B vaccine** | **HBIG** |
| Mother is HBsAg positive and HBeAg positive | Yes | Yes |
| Mother is HBsAg positive, HBeAg negative and anti-HBe negative | Yes | Yes |
| Mother is HBsAg positive where e-markers have not been determined | Yes | Yes |

| continued … | **Hepatitis B status of mother:** | **Baby should receive: Hepatitis B vaccine** | **HBIG** |
|---|---|---|---|
| | Mother had acute hepatitis B during pregnancy | Yes | Yes |
| | Mother is HBsAg positive and anti-HBe positive | Yes | **No** |
| | Mother is HBsAg seropositive &had HBA DNA level ≥1x$10^6$IUs/ml in an antenatal sample | Yes | Yes |

**Supply**: HBIG cannot be obtained without the approval of a Consultant microbiologist. This should be documented in the patient's medical notes.
It is stored in a fridge in Dr Hill's office. OOH please ensure you have read the appropriate policy before contacting the on-call microbiologist.

**Dose**: Give 200 international units of HBIG by IM injection as soon as possible after birth (**within 24 hours is adequate**). This should be ordered in advance of the birth.
The HBIG and vaccine can be given simultaneously but must be at different sites.

Where immunisation has been delayed beyond the recommended intervals, the vaccine course should still be completed but it is more likely that the child may become infected.

**Pre-term Babies: Babies with a birthweight of 1500g or less, born to mothers infected with hepatitis B, should receive HBIG, in addition to the vaccine, regardless of the e-antigen status of the mother**.
There is evidence that the response to hepatitis B vaccine is lower in pre-term, low-birth weight babies (Losonsky *et al*., 1999). It is, therefore, important that premature infants receive the full paediatric dose of hepatitis B vaccine (10mcg of Engerix B® brand) on schedule.

**Precautions**: When HBIG is being used for prevention of hepatitis B, it must be remembered that it may interfere with the subsequent development of active immunity from live virus vaccines.

- If immunoglobulin has been administered first, then an interval of three months should be observed before administering a live virus vaccine.
- If immunoglobulin has been given within three weeks of administering a live vaccine, then the vaccine should be repeated three months later.

## BCG (Bacillus Calmette-Guẻrin) VACCINE:

Those babies considered to be at 'high risk' of contact with active respiratory tuberculosis (TB) should be offered neonatal BCG immunisation after birth and before discharge where possible (-if not, then by the age of 3 months).

The following situations are deemed 'high risk' for infants (0-12 months):

- The infant will be a contact of a case of active TB (-contact the respiratory physician treating the active case for advice first and follow recommended contact management advice – see NICE CG117, 2006))
- There is a history of TB in immediate family members (parent, sibling, grandparent or other relative in regular contact with the family) within the previous 5 years
- The infant belongs to a family where one or both parents or grandparents were born in a country with a high annual incidence of TB (40/100,000 or greater - For country information on prevalence see: www.who.int/tb/country/data/profiles/en/index.html )
- The infant will reside in an area where the annual incidence of TB is considered to be high (40/100,000 or greater)
- The infant will travel to an area where the annual incidence of TB is considered to be high (40/100,000 or greater) for prolonged periods (more than three months)

The BCG vaccine is a **live** vaccine and should **not** be given to:

- a febrile infant
- Babies of HIV positive individuals – see above
- An infant who has received a course of steroids equivalent to po/pr prednisolone 2mg/kg/day for at least one week, or 1mg/kg/day for one month (see BNF for Children section 6.3 for table of equivalent anti-inflammatory doses of steroids). This does not include inhaled, topical or intra-articular steroids. Immunisation with live vaccines should be postponed for at least three months after treatment has stopped.
- Immunoglobulin may interfere with the immune response to live vaccines so the vaccine should be given at least 3 weeks before or 3 months after an injection of Immunoglobulin.
- Infants with evidence of impaired cell mediated immunity eg severe combined immunodeficiency syndrome.
- Patients receiving immunosuppressant drugs (eg azathioprine, ciclosporin). Immunisation with live vaccines should be postponed for at least six months after treatment has stopped.

**Dose**: The dose is 0.05ml for infants under 12 months. It must be given by intradermal injection just above the middle of the LEFT upper arm (LEFT recommended by WHO).

There is no need to delay primary immunisations when BCG is given but **no further immunisation should be given in the arm used for BCG immunisation for at least 3 months** because of the risk of regional lymphadenitis.

## IMMUNISATIONS FROM 2 MONTHS OF AGE

**PRIMARY IMMUNISATIONS** -Premature infants should be vaccinated according to their actual date of birth rather than their corrected gestational age. Therefore, the primary immunisation course should be commenced when a baby reaches two months of age (approx. day 60), and further doses given at three and four months as per the 2010 Green Book guidelines:

| Age | Immunisation | Vaccine Brand | Administration | Site |
|---|---|---|---|---|
| 2 months | Combined DTaP/Hib/IPV | Pediacel® | 0.5ml IM injection | Thigh |
| | Pneumococcal conjugate (PCV) | Prevenar 13® | 0.5ml IM injection | Thigh |
| | Rotavirus | Rotarix®* | 1.5ml PO dose | By mouth |
| 3 months | Combined DTaP/Hib/IPV | Pediacel® | 0.5ml IM injection | Thigh |
| | Meningococcal group C (MenC) | Menjugate® (powder)** | 0.5ml IM injection | Thigh |
| | | or NeisVac-C®** | 0.5ml IM injection | Thigh |
| | Rotavirus | Rotarix®* | 1.5ml PO dose | By mouth |
| 4 months | Combined DTaP/Hib/IPV | Pediacel® | 0.5ml IM injection | Thigh |
| | Pneumococcal conjugate (PCV) | Prevenar 13® | 0.5ml IM injection | Thigh |

*Rotavirus vaccine can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme,(including BCG vaccine), and so should ideally be given at the scheduled two month and three month vaccination visits (see above). It is suggested that Rotarix® is given before administration of intramuscular vaccines which may unsettle the infant.
Rotavirus and BCG can be given at **any time before or after each other**. (continued on next page…)

If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same vaccination visit. There are no restrictions on an infant's consumption of food or drink before or after the dose. (See below for further information)

**Although the summary of product characteristics for available MenC conjugate vaccines states that two doses should be given at least two months apart in those less than one year of age, evidence from a UK study shows that immunogenicity is adequate following a primary course of a single dose in infants (Findlow *et al*., 2012 – Green Book)). **For this reason, a second dose is no longer required at 4 months if the above brands are used.**
Meningitec® vaccine does not provide adequate protection against meningococcal serogroup C disease when administered as single dose in infancy, and is therefore no longer recommended for use in those less than 12 months of age. Should Meningitec® have been given as part of the infant schedule (for example inadvertently or overseas), a second dose of Men C vaccine (preferably one containing a CRM conjugate such as Meningitec® or Menjugate Kit®) should be given at least one month after the first dose

## ROTAVIRUS VACCINE:

Rotarix® should **not** be given to:
• infants with a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine
• infants with a confirmed anaphylactic reaction to any components of the vaccine
• infants with a previous history of intussusception
• infants aged 24 weeks of age or over (i.e. beyond 23 weeks and 6 days)
• infants presenting for the first dose of vaccine over 15 weeks of age
• infants with Severe Combined Immunodeficiency (SCID) disorder
• infants who have a malformation of the gastrointestinal tract that could predispose them to intussusception
• infants with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrose-isomaltose insufficiency

Administration of rotavirus vaccine **should be postponed** in infants:
• suffering from acute severe febrile illness. This is to avoid confusing the diagnosis of any acute illness by wrongly attributing any signs and symptoms to adverse effects of the vaccine
• suffering from acute diarrhoea or vomiting. This is to ensure that the vaccine is not regurgitated or passed through the intestines too quickly, which could reduce the effectiveness of the vaccine

**As Rotarix® is a live vaccine, can it be passed onto others?**
There is a potential for transmission of the live attenuated virus in Rotarix® from the infant to severely immunocompromised contacts through faecal material for at least 14 days, with peak excretion around the 7$^{th}$ day[1]. However, vaccination of the infant will offer protection to household contacts from wild-type rotavirus disease and outweigh any risk from transmission of vaccine virus to any immunocompromised close contacts.
Those in close contact with recently immunised infants should as always observe good personal hygiene e.g. washing their hands after changing a child's nappy.

**Can the vaccine be given to children who are immunocompromised?**
Rotavirus vaccine should not be administered to infants known to have severe combined immunodeficiency disorder (SCID). Although the vaccine is a live attenuated virus, with the exception of severe combined immune-deficiency (SCID), the benefit from vaccination may exceed any risk in other forms of immunosuppression. Therefore, there are very few infants who cannot receive rotavirus vaccine.
Given the high risk of exposure to natural rotavirus however, the benefit of administration is likely to outweigh any theoretical risks and therefore should be actively considered. Where there is doubt, appropriate advice should be sought from the child's paediatrician, an immunisation advisor or Consultant in Public Health rather than withholding vaccination.

For infants born to HIV-positive mothers, see section on page 1.

**Should rotavirus vaccine be offered to hospitalised infants?**
Infants, including those that are born prematurely should be offered rotavirus vaccine at their chronological age, if the infant is clinically stable.
Hospitalised pre-term infants are particularly vulnerable to rotavirus infection and its

complications and should be vaccinated as per recommendations. Delaying vaccination until discharge from hospital places the infant at a risk of acquiring the infection or receiving the vaccination too late and at a time where the risk of intussusception is greatest.

Rotarix® is a highly attenuated vaccine virus with a very low risk of clinical disease even in vulnerable infants. Infants vaccinated whilst in hospital do not need to be isolated from other infants. Aprons and Gloves should be worn for nappy changes and standard infection control precautions followed at other times to reduce the risk of transmission of the vaccine virus until discharge.
JCVI considered that the benefits of vaccination for this at-risk population at the appropriate time on neonatal units far outweighed any potential risk of transmission of this highly attenuated vaccine virus.

**RESPIRATORY SYNCYTIAL VIRUS (RSV) -** See individual guidelines for information

## POST IMMUNISATION MONITORING IN PREMATURE INFANTS:

It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule. The occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely.

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 child 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 (Green Book).

As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

**Any suspected reactions in children should be reported to the Commission on Human Medicines using the Yellow Card Scheme**

***Any queries regarding immunisation should be directed to Dr Sarah Morris, PHFT Child Health Immunisation Advisor*.**

Further information can also be obtained from the website: **www.immunisation.nhs.uk**

References – Department of Health Publications:
1- Personal communication with Medical Information at GSK wrt Rotarix excretion – D Terrot, 9th Jan 14
Immunisation against infectious disease - The Green Book 08/2006 – contra-indications and special considerations chapter updated 01/2013, Immunisation of individuals with underlying medical conditions chapter updated 03/2011, primary immunisation chapter updated 12/2010, meningococcal chapter updated June 2013, tuberculosis chapter updated 07/2011
Changes to the BCG Vaccination Programme – 06/07/2005,
Important Changes to the Childhood Immunisation Programme – 12/07/2006,
NICE (National Institute for Health and Clinical Excellence) Clinical Guideline 117 – Tuberculosis 03/2011
BHIVA (British HIV Association) Guidelines for the Management of HIV infection in pregnant women 2012 – HIV Medicine (2012); 13 (suppl 2): 87-157
PHE – Public Health England: The infant rotavirus vaccination programme – Q&As for healthcare practitioners v4 26th July 2013