Hepatitis B Immunisation

The prevalence of hepatitis B in antenatal women is 0.14% (varying between 0.05 and 1% in certain areas). Infants of mothers who are Hepatitis B surface antigen (HBsAg) positive in pregnancy are at risk of acquiring the infection by vertical transmission. It is therefore necessary that infected mothers are identified during pregnancy, and arrangements made for their babies to receive a complete course of immunisation. By vaccinating the newborn soon after birth and then later in infancy, the risk of transmission can be reduced from almost 90% to < 5%.

The risk of transmission is highest if the mother is hepatitis B e-antigen (HBeAg) positive, but the risk is low if the mother is Hepatitis B e-antibody (Anti HBe) positive. It is therefore essential to establish the antigen and antibody status of the mother, as the management of high and low risk babies differs. Hepatitis B screening is routinely performed antenatally, and the antibody status of positive women will be elucidated. Breast feeding is not contraindicated unless the mother is also HIV positive.

High Risk

Mothers who are Hepatitis B surface antigen (HBsAg) positive plus:

- e-antigen positive and e-antibody negative (HBeAg+ and Anti HBe-); or
- e-antigen negative and e-antibody negative (HBeAg- and Anti HBe-); or
- e-status of mother unknown; or
- Acute hepatitis during pregnancy

These babies are at high risk of acquiring Hepatitis B and must receive combined immunisation with vaccine and immunoglobulin:

1. Hepatitis B immunoglobulin (HBIG) 200iu IM anterolateral thigh
2. Hepatitis B vaccine (Engerix B) 0.5ml IM contralateral thigh

The vaccine should be given as soon as possible after birth. The immunoglobulin is available either in the fridge on Labour Ward or by contacting the pharmacy department and should be given within 24 hours of birth. See pages 5 and 6 for administration details.

Premature or low birth weight babies

There is evidence that the response to Hepatitis B vaccine is lower in preterm, low birth weight babies (Losonsky et al., 1999). It is important that premature infants receive the full paediatric dose of Hepatitis B vaccine on schedule. All babies who weigh less than 1500g at birth and whose mothers are HBsAg positive require HBIG in addition to the vaccine, regardless of the maternal e-antigen status.
**Low Risk**

If the Mother is Hepatitis B surface Antigen (HBsAg) positive and e-antibody (Anti HBe) positive the baby is at **low risk** of acquiring hepatitis B and therefore does not require immunoglobulin. They require active immunisation as soon as possible after birth, within 24 hours:

Hepatitis B vaccine (Engerix B) 0.5ml IM anterolateral thigh

If there are any household contacts that are Hepatitis B positive, the baby can receive immunisation as above.

**Subsequent arrangements**

1. Complete the letter overleaf to the GP (they will arrange for further vaccinations of Hepatitis B at 1 and 2 months, and boosters at 1 and 5 years).

2. Give the parents a copy of the parent information sheet.

3. Ask the ward clerk for a **Hepatitis B immunisation insert for the red book** and record that the first dose of vaccine has been given (including manufacturer and batch number).

4. Ask the Joan Booker ward clerk to **make up a set of notes for the baby** and to file a copy of the GP letter. Ask them to send copies of the GP letter to the health visitor, to Debbie Evans on the neonatal unit, and to Dr. Margot Nicholls at the Health Protection Agency (address on GP letter). They should also **arrange the outpatient appointment at 14 months** with the attending Consultant.

5. Debbie Evans will update the Hepatitis B database. She will send a letter at 1 year to remind parents that the baby is due their booster and she will also send a form for their 13 month blood tests.

6. At 13 months the baby will have blood tests for LFT's and Hepatitis B serology (HBsAg and AntiHBs titres) to assess if the baby has become chronically infected with hepatitis B and to measure the antibody response. The baby will be seen in outpatients at 14 months to discuss the results. If there is evidence of chronic infection or inadequate antibody response, the case should be discussed with a Microbiologist.
Hepatitis B Immunisation

Baby’s name: 
Baby’s D.O.B: 
Hospital number: 

Mother’s addressograph: 

Date: ___________  Consultant Paediatrician: ________________

Dear Doctor ____________________

This patient is on the Hepatitis B Immunisation Programme. **Further doses of Hepatitis B vaccine are required to complete the course, and we would be grateful if this could be arranged through your practice**

- The next two at 1 and 2 months of age
- A booster at 1 year of age and pre-school booster at 5 years

**Subsequent arrangements**
A reminder will be sent out to you and the parents at 12 months indicating that a booster is due. They will also be sent a form to have blood tests at 13 months to identify babies who have acquired hepatitis B, and to assess if there has been an adequate antibody response. The baby will be reviewed in our Outpatient Department at 14 months to discuss the results. Further doses of vaccination may be necessary.

The Hepatitis B vaccine does not interfere with any of the other immunisations in the infant schedule, and they can be given as normal.

Please do not hesitate to contact us should there be any problems regarding the further Hepatitis B Immunisations.

Yours sincerely,

Dr. ______________

Copies to:
Debbie Evans, Neonatal Unit
Health Visitor
Dr Margot Nicholls, Consultant in Communicable Disease Control, Health Protection Unit, County Hall North, Chart Way, Horsham, West Sussex, RH12 1XA
Hepatitis B Immunisation
Information for Parents

Baby’s name:
Baby’s D.O.B:
Hospital number:

Mother’s addressograph:

Date:__________  Consultant Paediatrician__________________

Dear Parent,

Your baby has received his/her first Hepatitis B vaccine. Further doses are required to complete the course, these are:

- The next two at 1 and 2 months of age
- A booster at 1 year of age and pre-school booster at 5 years

These should be given by your GP practice, and a letter has been sent to them and your baby’s Health Visitor

Subsequent arrangements
You will be sent a letter at 1 year to remind you that your baby’s hepatitis B vaccine booster is due. You will also be sent a form to have blood tests to check the baby’s Hepatitis B status and their antibody levels at 13 months. Your baby will be reviewed in our Outpatient Department at 14 months to discuss the results. It may be necessary to give further doses of the vaccine.

Your baby can receive all their other routine vaccines at the usual times.

Yours sincerely,

Dr. ____________________________

Designation ______________________
Hepatitis B Immunisation

There are 2 types of immunisation product, a vaccine which produces an active immune response, and a specific immunoglobulin which confers immediate but temporary passive protection.

**Hepatitis B active Immunisation**
This product consists of inactivated Hepatitis B surface antigens. It should be stored at 2-8 °C but not frozen.

At risk babies should receive the “accelerated schedule” (see above) and 80 – 90% will mount a response. Antibody levels (Anti HBs) should be taken 1 months after completion of this course, i.e. at 13 months, to assess the response.

- Levels < 10miu/ml = non responders – will need a repeat course
- Levels > 100miu/ml = protective
- Levels 10 – 100miu/ml = poor responders – will need booster dose

If levels are not protective, the results will be discussed with one of the Consultant Microbiologists (Drs Grundy/Shaw/Kirk). Testing for HBsAg at 13 months will identify babies who have become carriers, and will allow them to be referred for assessment and further management.

The exact duration of antibody persistence is not precisely established (Whittle et al 2002). Recent evidence suggests that a single booster 5 years after completion of a primary course is sufficient to retain immunity in those who continue to be at risk of infection. It is therefore recommended that children born to Hepatitis B mothers receive a booster as part of their pre – school immunisations.

**Administration**
It must be given intramuscularly, and the preferred site in infants is the anterolateral thigh. It must not be given in the buttock as vaccine efficacy may be reduced. It can be administered at the same time as any other vaccination, but should be given at a separate site (at least 2.5cm away – American Academy Pediatrics 2003) and preferably in a separate limb.

**Dose**
We currently use Engerix B and the dose is 10mcg (0.5ml)

**Adverse reactions and contraindications**
Hepatitis B vaccine is generally well tolerated and the most common adverse reactions are soreness and redness at the site of injection. Other reactions which have been reported include fever, rash, malaise and an influenza – like syndrome, arthritis, arthralgia, myalgia and abnormal liver function tests.
Administration of the vaccine should be delayed in individuals suffering from severe febrile illness.
The vaccine may be given to HIV positive individuals.

**Hepatitis B Immunoglobulin (HBIG)**
Specific Hepatitis B Immunoglobulin (HBIG) is available for passive protection and is normally used in combination with Hepatitis B vaccine as part of a combined immunisation programme.
It is given at the same time, but a contralateral thigh to the vaccination. Passive immunisation with HBIG will not suppress the active immune response conferred by the Hepatitis B vaccine.
If infection has occurred already, the severity of the illness will likely be reduced, and the
development of carrier state may be prevented.

In babies born to Hepatitis B positive mothers, it should be given not later than 24 hours
after birth.

**HBIG**
This is obtained from the plasma of immunised and screened human donors. Because of
the theoretical risk of transmission of CJD from plasma products, HBIG is now prepared
from plasma sources outside of the UK and supplies are scarce.
It should be stored at 2–8 °C.

**Dose**
Newborns require 200iu (2ml) as soon as possible after birth. It will be necessary to split this
into 2 doses of 1ml into separate sites 2.5 cm apart for term babies. For preterm babies
please discuss with the attending Consultant. It is likely that the HBIG will be given in small
0.5ml aliquots in sites at least 2.5cm apart.

**Adverse reactions and Contraindications**
HBIG is well tolerated. Very rarely anaphylactoid reactions occur in individuals with
hypogammaglobulinaemia who have IgA antibodies, or those who have an atypical reaction
to blood transfusions. No cases of blood borne infections from Ig designed for IM use have
been documented.

**References**


vaccination during infancy in a country where endemicity is low. J Infectious Dis 190:
1264-9

3) Immunisation against Infectious Disease (Green Book) 1996, Department of Health

(2): 14

5) New Chapter 19, Hepatitis B, Immunisation against Infectious Disease (Nov 2005),
Department of Health

6) Whittle et al (2002) Observational study of vaccine efficacy 14 years after trial of
Hepatitis B vaccination in Gambian children. BMJ 325: 569-73

beginning at birth and to subsequent booster vaccination. Paediatr Infect Dis J. 22:
157-63

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