IMMUNISATIONS

IMMUNISATIONS IN THE NEONATAL PERIOD

1. DTaP/IPV/Hib
2. Meningitis C
3. Pneumococcal conjugate vaccine (PCV)
4. BCG
5. Hepatitis B

These guidelines have been drawn up to ensure a coherent practice from all neonatal staff involved in immunisation.

Consent

Immunisation is given to all well infants. As it is not therapy for an existing disease parental consent is required. Written consent provides a permanent record and is considered best practice.

One possible exception is in the case of HepB Ig administration to high risk infants. Please see separate section below.

Documentation

- All Vaccines must be prescribed
- Vaccine batch numbers should be recorded on the drug prescription sheet.
- Vaccinations should be noted centrally on the appropriate forms
- Vaccinations should be recorded in Red Books and on discharge summaries for UNIT patients.

Specific Immunisations

1. DTaP/IPV/Hib

Diptheria, tetanus, acellular pertussis (DTaP) and inactivated polio vaccine (IPV) now come combined with that for Haemophilus Influenza type b (Hib). Pediacel and five component vaccine is now available and is recommended for primary immunisation by the Joint Committee on Vaccination and Immunisation.

Pediacel is used for primary immunisation of infants at 2, 3 and 4 months of age. This five component vaccine has three possible advantages:

- IPV provides effective individual protection without the risk of causing vaccine associated paralytic polio, which occurred very rarely with oral polio vaccine (OPV). The risk of 'wild' polio virus has declined considerably due to the success of the WHO Polio Eradication Programme. Thus the benefit of community cover with live OPV is no longer as vital.
• The acellular pertussis vaccine causes less adverse reactions without compromise to cover. The acellular pertussis vaccine has been shown to offer equal or better protection than whole-cell vaccine. There is no benefit in withholding acellular pertussis-containing vaccines to reduce adverse events as the incidence of reactions to DTaP is similar to that for DT.

• There is no thiomersal (ethylmercury) in Pediacel hence reducing exposure to mercury.

Possible Adverse Reactions (that need reporting):
Fever to > 39.5°C within 48 hours
Indurated red swelling at site of injection (classified as local reaction)
Acute anaphylaxis
Acute bronchospasm
Laryngeal oedema
Generalised collapse
Prolonged unresponsiveness
Inconsolable or high pitched cry for more than 4 hours
Convulsions or encephalopathy within 72 hours.

Pharmacy Issues – presentation, storage, dosage and administration

Pediacel (DTaP/IPV/Hib) is manufactured by Aventis Pasteur MSD and is supplied as a suspension in a single dose vial. The vial should be shaken well before the vaccine is drawn up in a syringe for administration.

Storage
All of the new vaccines should be stored between +2°C and +8°C and protected from light. If a vaccine has been frozen, it must not be used as this can reduce its potency and increase local reactions.

Vaccines should be disposed of by incineration at a suitably authorised facility.

Administration
The vaccines should be inspected visually for extraneous particulate matter and/or discolouration prior to administration. In the event of either being observed, the vaccine must be discarded.

The vaccines should be administered intramuscularly as this reduces the risk of local reactions. Administration by deep subcutaneous injection may be considered for patients suffering from bleeding disorders, such as thrombocytopenia, because this reduces the risk of haemorrhage.

Contraindications
There are very few individuals who cannot receive Pediacel. The vaccine should not be given to those who have had:

• A confirmed anaphylactic reaction to a previous dose of diphtheria-, tetanus-, pertussis- or polio-containing vaccine; or
• A confirmed anaphylactic reaction to neomycin, streptomycin or polymyxin B (which may be present in the vaccine in trace amounts).

Withhold DT&P/IPV/Hib in the following:

- Babies who are acutely ill or febrile.
- Severe local or generalised reaction to previous vaccine dose.
- Babies on intensive care whose condition is unstable.
- Babies on steroids for chronic lung disease (does not include inhaled steroids)

Reporting of adverse reactions

Pediacel carries a black triangle (?) symbol. This is a standard symbol added to the product information of a vaccine/medicine during the early stages of marketing to encourage reporting of all suspected adverse reactions. If a doctor, nurse, or pharmacist suspects any adverse reaction to one of these vaccines has occurred, they should report it to the Committee on Safety of Medicines using the Yellow Card spontaneous reporting scheme (www.yellowcard.gov.uk).

2. MENINGITIS C VACCINATION

Since 1999 all babies have been offered vaccination against Meningitis C as part of the standard immunisation schedule, given with the DPT-Hib and Polio at two, three and four months of age. Evidence so far suggests the vaccine is highly effective; the first winter after its introduction showed a 75% reduction of the incidence of Group C meningococcal disease in children under one year of age and those between 15 and 17 years (the two target populations). This trend has continued.

Dose: 0.5 ml IM in arm or leg (not used for any other vaccine on same occasion) at 2,3 and 4 months.

Patients who should NOT receive Meningitis C vaccination are:

- Babies who are acutely unwell or febrile.
- Babies who have had a hypersensitivity reaction to any constituent of the vaccine including meningococcal C polysaccharide, diptheria toxoid or the CRM197 carrier protein or tetanus toxoid.

The main side-effects are fever, soreness and inflammation at the injection site. Older children may experience dizziness, headaches, nausea and vomiting.

3. PNEUMOCOCCAL CONJUGATE VACCINE

Pneumococcal vaccines protect against infection with \textit{Streptococcus pneumoniae} (pneumococcus); the vaccines contain polysaccharide from capsular pneumococci. Pneumococcal polysaccharide conjugated vaccine contains polysaccharide from 7 capsular types, the polysaccharide being conjugated to protein.
# Schedule of Immunisations for Childhood

<table>
<thead>
<tr>
<th>When to immunise</th>
<th>What is given</th>
<th>How it is given</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months old</td>
<td>Diptheria, tetanus, pertussis (whooping cough), polio and <em>Haemophilus influenzae</em> type b (Hib) (DTaP/IPV/Hib)</td>
<td>One injection</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal infection (Pneumococcal conjugate vaccine, PCV)</td>
<td></td>
</tr>
<tr>
<td>3 months old</td>
<td>Diptheria, tetanus, pertussis, polio and <em>Haemophilus influenzae</em> type b (Hib) (DTaP/IPV/Hib)</td>
<td>One injection</td>
</tr>
<tr>
<td></td>
<td>Meningitis C (meningococcal group C) (MenC)</td>
<td>One injection</td>
</tr>
<tr>
<td>4 months old</td>
<td>Diptheria, tetanus, pertussis, polio and <em>Haemophilus influenzae</em> type b (Hib) (DTaP/IPV/Hib)</td>
<td>One injection</td>
</tr>
<tr>
<td></td>
<td>Meningitis C (meningococcal group C) (MenC)</td>
<td>One injection</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal infection (Pneumococcal conjugate vaccine, PCV)</td>
<td>One injection</td>
</tr>
<tr>
<td>Around 12 months old</td>
<td><em>Haemophilus influenza</em> type b (Hib) and meningitis C (Hib/MenC)</td>
<td>One injection</td>
</tr>
<tr>
<td>Around 13 months old</td>
<td>Measles, mumps and rubella (German measles) (MMR)</td>
<td>One injection</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal infection (PCV)</td>
<td>One injection</td>
</tr>
<tr>
<td>3 years and 4 months to 5 years old</td>
<td>Diptheria, tetanus, pertussis (whooping cough) and polio (dTaP/IPV or DTaP/IPV)</td>
<td>One injection</td>
</tr>
<tr>
<td></td>
<td>Measles, mumps and rubella (MMR)</td>
<td>One injection</td>
</tr>
<tr>
<td>13 to 18 years old</td>
<td>Diptheria, tetanus, polio (Td/IPV)</td>
<td>One injection</td>
</tr>
</tbody>
</table>
4. **BCG VACCINATION**  
*(Princess Royal Hospital)*

Newborn infants can be protected from TB by the BCG vaccine. In the UK, immunisation is targeted at those infants most at risk. The population screening programme at age 13 is to be discontinued. It is important therefore that all eligible newborn infants are identified and immunised as soon as possible after birth.

BCG vaccine contains a live-attenuated strain of *Mycobacterium bovis*.

Adverse reactions are rare providing attention is paid to correct administration technique.

It is recommended that the following groups are immunised as soon as possible after birth:

- Infants in a family with a history of TB
- Infants of parents requesting BCG vaccination for their children
- All infants living in areas where the incidence of TB is greater than 40/100,000 (see attached list of nations)
- Infant whose parents or grandparents were born in a country where the incidence of TB is greater than 40/100,000 (see attached list of nations)
- Previously unvaccinated infants arriving from a country where the incidence of TB is greater than 40/100,000 (see attached list of nations)
- Infants returning to a country where the incidence of TB is greater than 40/100,000 (see attached list of nations) for a period of one month or more
- In practice, consider all nations from Asia, Africa and South America to be included in this list. Some Eastern European states are also included.

The following are contra-indications to BCG vaccination:

- Suspected immunocompromisation (eg hypogammaglobulinaemia)
- Recent corticosteroid or other immunosuppressive therapy
- Infants suspected to be HIV positive, **including** those born to HIV positive mothers
- Infants who are febrile
- Infants with generalised septic skin conditions

Infants under **12 months** of age can be offered BCG vaccine without prior Mantoux testing providing there is no reason to suspect that the infant has been exposed to TB.

**At RSCH:**

Health visitors are responsible for referring eligible infants for BCG referral.

Referrals can be made by completing a BCG Immunisation Referral Form (kept on the L12 trolley). This should be sent to the School Clinic at Morley Street.

**At PRH:**

- Infants are identified by the ANNPs / Staff Grades postnataally and BCG vaccination arranged before discharge
Infants can return to SCBU for vaccination in the neonatal period if
- Vaccination is not performed before discharge
- Referral is made by community health care professionals

Administration

- Parents should sign the consent form
  (insert this in parent-held health record / hospital notes)
- BCG vaccine should be given intradermally using a separate tuberculin syringe and needle for each subject
- The multi-dose vial should be stored at 2-8 degrees Celsius, be protected from light and never frozen. It should not be used after the expiry date displayed on the label
- The multi-dose vial should be diluted as instructed using aseptic precautions with the diluent supplied. Once diluted, the vaccine must be used within 2 hours and thereafter discarded
- The recommended site is the insertion of the deltoid muscle on the left upper arm (higher sites are more commonly associated with keloid formation). An alternative site is the upper, lateral aspect of the left thigh
- 0.05ml (0.1ml if more than 3 months of age) should be given using a clean syringe and orange needle (26G)
- Hold the arm in the palm of one hand
- Clean the skin with spirit and allow to dry
- Advance the needle, bevel uppermost, intradermally 2mm into the skin. The needle should be visible beneath
- Injection should result in a raised tense bleb of up to 7mm diameter. There should be some resistance to injection felt
- No other immunisation should be given in the BCG arm for at least 3 months due to the risk of regional lymphadenitis
- Sign the drug chart and record the batch number
- Record the vaccination in the child’s parent-held health record (red book)
- Complete GP notification form
- Complete Child Health notification form

Advice to parents

- A local reaction at the site should develop within 2 to 6 weeks, beginning as a small papule which increases in size and may bruise, crust or scale
- The site should be left exposed to the air to allow rapid healing with minimal scarring (it is not necessary to dress the site or to protect it from bathing)
- If any oozing does occur, a dry dressing may be applied until a scab forms
- The lesion slowly subsides over a period of months leaving a smooth, flat scar
- Rare adverse reactions include local adenitis and keloid formation (both mostly avoided by correct siting and administration)
- No other immunisation should be given in the BCG arm for at least 3 months due to the risk of regional lymphadenitis
5. HEPATITIS B VACCINATION

From August 1999 all mothers will have routine serology for Hepatitis B and HIV (see HIV Protocol) at booking. Blood samples from mothers who are identified as HbsAg carriers are sent to the reference laboratory for full assessment of e Antigen status in order to allow the microbiology department to order a dose of Hepatitis B immunoglobulin on a named patient basis.

Those considered at high risk:
- Ethnic mothers from China, SE Asia, sub Saharan Africa, Eastern Europe.
- Previous exposure.
- Sexual exposure risk group
- Past or current IV drug abuse
- Hep C positive mothers
- Family history
- Occupational exposure risk (Health, Prison and Residential Care Home staff)

Maternal blood tests

Low risk of perinatal infection: only hepatitis B vaccination is required:
- Mothers who are just HepBsAg +ve only (not as a result of vaccination)
- Mothers who are HBsAg+ and anti-HBeAb positive

High risk of perinatal infection: Hep B vaccination and immunoglobulin required:
- mothers who are HBeAg+
- Babies born to mothers who have had acute hepatitis B during pregnancy.

Any doubts over antibody status or the question of immunoglobulin should be discussed with a Consultant microbiologist. If the mother’s status is not determined and urgent testing is not possible (late presentation, testing unavailable over a weekend, then immunoglobulin should be obtained urgently and given. The maternal status can be performed later.

Vaccination should take place at birth, 1, 2 and 12 months of age with follow up antibody status at 14 months in babies born to mothers who:
- are chronic carriers of hepatitis B virus (HbsAg +ve)
- have suffered from acute hepatitis B during pregnancy

GP and health visitor must be notified prior to discharge as they will need to administer the final three vaccine doses.

Following delivery:

Vaccination should be given within the first few hours after delivery (less than 12 hours).
If immunoglobulin is required this is especially important. The dose of immunoglobulin is 200 units intramuscularly as soon as possible after birth.
The hepatitis B consent form should be signed by the mother after birth (if this has not been done in the antenatal period) and given to her. This form is an extra insert which she should place inside the red child health record book along with other records of childhood vaccinations when this is supplied by the Health Visitor. (this should be explained to the mother).

Many of the midwives are happy to obtain consent and administer the vaccine. Some will not feel confident to do so and will call the doctor/ANNP responsible for the postnatal ward.

At the routine first day check:
- Make sure that the required vaccinations have been given.
- Make sure the Hepatitis B notification form has been filled in
- Send the top copy of the notification form to the GP and make copy for health visitor (there is no need to do an additional post-natal discharge form)
- Put the second copy of the notification form in the internal post addressed to Child Health Clinic, Morley St.
- Make sure that the consent is signed and the mother has been given the consent form/insert for the red child health record.

Further vaccinations, recall for booster at 12 months and measurement of antibody levels should then take place in the community.

5. HEPATITIS C

The predominant sources of hepatitis C are sharing needles in injecting drug users and from blood transfusions. Transmission is possible by sexual contact but is unusual. Within the first 2 years of injecting there is a 10% chance of being infected. This rises to 75% after an injecting career of 15 years. Reports of Hep C infection have risen from 200-300/yr in 1992 to 1500/yr in 1995 and 5000/yr in 1999. There has been a slight drop since that peak.

Currently routine antenatal screening is not undertaken for Hepatitis C. Screening should be undertaken for high risk groups.

Infection in adults can symptomatic or asymptomatic. 20% recover completely. 80% continue to have chronic infection: this can involve persistent viraemia, or chronic liver infection. One in 5 of these will get cirrhosis and some will progress to liver cancer.

The overall risk for perinatal transmission for mothers who are Hepatitis C antibody positive from a number of studies is approximately 6-8%. There is some suggestion that those mothers who are not viraemic (Hep C RNA not detected by PCR) in the last trimester of pregnancy may have a much lower risk than this. The babies of these mothers still need to be screened for Hepatitis C. Co-existent HIV infection in the mother increases the chances of perinatal transmission to 15-20%.

Pre-conception:
Mothers may wish to delay pregnancy and undergo treatment (usually interferon) to clear the virus (become PCR negative) prior to conception. There is not enough evidence in the literature yet to suggest that post-natal testing of the baby is not necessary.
**Pregnancy**
Once the diagnosis has been made, referral should be sent via the neonatologists to the neonatal viral clinic. An ante-natal appointment should be offered to explain the risks of perinatal transmission and post-natal testing should be offered. Breastfeeding plans should also be discussed (see below). There is no evidence that opting for a caesarean section reduces the risk of infection (unlike HIV infection).

**Breastfeeding:** There has not yet been a reported incidence of an infant in the medical literature who has been infected solely through breastfeeding. Unlike HIV infection (where there can be transfer of infected lymphocytes through breast milk) there is not a postulated mechanism whereby one would expect infection to be transmitted. There is a theoretical chance that infection could be passed on if there are bleeding nipples. So although one could not be categorical that infection couldn’t ever happen from breastfeeding, the risk is clearly extremely small (?negligible), and most medical advisers recommend that the enormous advantages of breast-feeding outweigh the theoretical risk, however each mother must come to her own decision.

**Postnatal**
Due to the presence of maternal antibody, it is not possible to tell the status of the baby until they are at least 12 months old. Most authorities would repeat the Hep C antibody test again at 18 months or 2 years to be sure.

Previously there was no recommended treatment for Hep C infection in infants, therefore there was no reason to know the status of the baby until it was possible to take a definitive test at 12 months. Although interferon is not yet a standard treatment for neonates with Hep C infection, there are trials being undertaken at liver units to assess its use. It is therefore appropriate to refer all babies to King’s College Hospital Liver Unit who have evidence of infection (abnormal LFT’s, or positive PCR or positive antibody test at >12 months old). Additionally, many parents find that it is a long time to wait for the result, and are anxious to know sooner.

Currently, three HIV RNA PCR’s are taken: within a few days of birth, at 1 month, and again at three months. If these are all negative then there is a greater than 99% chance that the baby is not infected. To be 100% sure, the antibody test will still need to be undertaken.

| 24-72 hours | General clinical examination  
Blood tests:  
Hep C PCR (1ml, pink EDTA tube)  
FBC and differential  
LFT’s (including gamma GT)  
*Label clinic code NOPD on blood forms*  
Appointment made in neonatal viral clinic for 1 month |
|---|---|
| 4 weeks | History: ?unwell at all  
Examination: (especially) growth, liver/spleen  
Hep C PCR  
LFT’s (inc. gamma GT) |
<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Details</th>
</tr>
</thead>
</table>
| 12 weeks  | History: unwell at all  
Examination: (especially) growth, liver/spleen  
Hep C PCR  
LFT’s (inc. gamma GT) |
| 13-14 weeks | If 3rd set of PCR results negative: telephone parents and arrange appointment in viral clinic for 12 months of age  
If results positive, arrange clinic appointment for 16 weeks at which results can be discussed and referral made to King’s College Hospital Paediatric Liver Unit |
| 12 months | History & General clinical examination  
Hepatitis C antibody and PCR  
LFT’s (inc. gamma GT) |
| 18 months | History & General clinical examination  
Hepatitis C antibody and PCR  
LFT’s (inc. gamma GT) |
Blood bottles: LFT’s: microtainer with green cap (clotted sample)

Hep C Ab & PCR: EDTA microtainer with purple cap normally used for full blood count. Please give them TWO bottles if you can, if not then make sure on the form that the lab prioritise the PCR rather than the antibody test.

Label the blood forms “NOPD” (not UNIT or a consultant name), so that the results get sent back to the secretaries and don’t get buried in thousands of results that get sent back to UNIT.

At the moment the antibody levels are not quantified, so it is not possible to observe declining levels of maternal antibody. It is not necessary to keep measuring the presence of maternal antibody in the first few months.

Neil Aiton Sep 2005

References:

New Vaccinations for the Childhood Immunisation Programme. Department of Health Publications August 2004. dh@prolog.uk.com

The Green Book WWW.immunisation.nhs.uk

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