Guideline

Women and Babies: Routine Immunisation in Newborn Care

Document No: RPA H_GL2014_001
Functional Sub-Group: Clinical Governance
Summary: This guideline provides information to ensure the safe storage and administration of routine immunisations in the newborn.

National Standard: Standard 4 - Medication Safety
Policy Author: Clinical Nurse Consultant Perinatal Nursing
Approved by: Head of Department RPA Newborn Care General Manager
Publication (Issue) Date: February 2014
Next Review Date: February 2019
Replaces Existing Policy: Immunisation: Routine administration in Newborn Care June 2009
Previous Review Dates: June 2013
Women and Babies: Routine Immunisation in Newborn Care

1. Introduction
Immunisation protects children from harmful infections before they come into contact with them in the community. This Policy follows guidelines recommended by the National Health and Medical Research Council (NHMRC) \(^1\).

The risks addressed by this policy:
- Maintenance of the cold chain will ensure the integrity of vaccines is maintained.
- Correct administration of vaccines will optimise the wellbeing of the term and preterm infant discharged from RPA Women and Babies.

The aims / expected outcome of this policy
To safely immunise the term and preterm infant according to the National Immunisation Programme Guidelines\(^1\).

2. Policy Statement

The main change in this revised guideline is the introduction of hepatitis B immunisation for all infants at birth regardless of gestational age, as per the Australian Immunisation Handbook (2013).

This guideline will assist midwives, registered nurses and medical officers to provide parents with the relevant information about childhood immunisation and ensure parental consent is documented before routine immunisation of their infant.

3. Principles / Guidelines

3.1 Delivery of Vaccines to Newborn Care
Deliveries from pharmacy will be in an appropriate cold storage device to maintain the cold chain. On arrival in the nursery immediately place immunisations into the dedicated refrigerator in the Special Care Nursery on the middle shelf. Refrigerator cleaning should be done as per the Strive for 5 Guidelines\(^2\). If vaccines inadvertently freeze during storage they must be discarded.

3.2 Storage of Vaccines
The registered nurse in charge of the Special Care Nursery should check and document refrigerator temperature (minimum-maximum) twice each day. Vaccinations must be stored between 2-8°C. If the cold chain has been broken i.e. fridge thermometer shows temperatures outside the range of 2-8°C or vaccines have been left out of refrigeration then do not use. Inform the Newborn Care pharmacist on pager 81054 and organise return of the vaccines to pharmacy.
The immunisation refrigerator is alarmed and under a service contract with ROLLEX Medical. In the event of failure the RN in charge of shift must notify ROLLEX Medical (contact details on refrigerator door). All vaccines should be moved to the TPN (total parenteral nutrition) refrigerator (alarmed).

3.3 Routine vaccines used in Newborn Care

3.3.1 Hep B immunoglobulin (HBIG) (100 international units) – This product is not kept on the unit and must be obtained from the RPA Blood Bank. Take infant’s medication chart and a completed RPA – Blood Product Issue Form to Blood Bank for issue – see below for guidelines regarding administration and documentation.

3.3.2 H-B-VAX II (5mcg/0.5ml) – hepatitis B

3.3.3 Infanrix hexa (DTPa-hepB-IPV-Hib) – hepatitis B, diphtheria, tetanus, acellular pertussis (whooping cough), Haemophilus Influenzae type b, inactivated poliomyelitis (polio).

3.3.4 Prevenar 13 - pneumococcal conjugate vaccine 13vPCV

3.3.5 Rotarix® - oral rotavirus vaccine

If another non routine vaccine is ordered – please confirm dose, method of administration and precautions in the Australian Immunisation Handbook before giving.

3.4 Parental Consent

Informed consent must be obtained from the parents/guardians prior to immunisation. Provide information regarding the risks and benefits of immunisation. ‘Understanding Childhood Immunisation’ brochure should be in the Personal Health Record (Blue Book).

This book may be downloaded from the internet in 16 different languages – see link below.

Allow time for discussion and questions and provide additional information as requested by parents. Document consent in medical record. If parents decline consent, the registered nurse in charge of shift is to inform the staff specialist on service. Document subsequent process / discussions in the progress notes and Blue Book.
3.5 Prescribing and infant monitoring

Immunisations must be prescribed by a medical officer or nurse practitioner and all preterm infants are monitored for apnoea for 24 hours following Infanrix hexa & Prevenar immunisations. Administer at least 48 hours before discharge.

Ensure that all resuscitation equipment is available & functioning prior to administration of vaccines

3.6 Current Immunisation Schedule as of 1st July 2013

<table>
<thead>
<tr>
<th>Timing</th>
<th>Disease</th>
<th>Vaccination</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ALL infants of mothers who</strong></td>
<td><strong>Hepatitis B</strong></td>
<td>Hep B immunoglobulin (HBIG) dose is 100 international units</td>
<td>Must use opposite thighs for each vaccine - (R) <strong>AND</strong> (L) thigh</td>
</tr>
<tr>
<td><strong>are Hep B Surface Antigen</strong></td>
<td><strong>Within 12 hours of birth</strong></td>
<td>H-B-VAX II (5mcg)</td>
<td></td>
</tr>
<tr>
<td><strong>positive</strong></td>
<td>(but HBIG may be given up to 48 hours)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ALL Infants at birth</strong></td>
<td><strong>Preferably within 24 hours of birth</strong></td>
<td>Hepatitis B</td>
<td>Use (R) <strong>OR</strong> (L) thigh</td>
</tr>
<tr>
<td></td>
<td>(but up to &amp; including day 7)</td>
<td>H-B-VAX II (5mcg)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>At 8 weeks of age if well</strong></td>
<td>Infanrix hexa (DTPa-hepB-IPV-Hib)</td>
<td>Use (R) <strong>OR</strong> (L) thigh</td>
</tr>
<tr>
<td></td>
<td><strong>Diphtheria, tetanus, Acellular pertussis,</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>hepatitis B, Haemophilus influenzae</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>inactivated poliomyelitis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Pneumococcal</strong></td>
<td>Prevenar (pneumococcal conjugate vaccine 13vPCV)</td>
<td>Use other thigh</td>
</tr>
<tr>
<td></td>
<td><strong>Rotavirus</strong></td>
<td>Rotarix® 1st dose 6-14 weeks of age interval separating doses should be no less than 4 weeks</td>
<td>Oral live vaccine 2 doses – 1 each at 2 &amp; 4 months</td>
</tr>
</tbody>
</table>

Ensure that all resuscitation equipment is available & functioning prior to administration of vaccines
3.7 Administration

3.7.1 Rotarix®

This is an ORAL vaccine and may be administered via an intra-gastric tube or, in the mature infant, while sucking through a teat.

The two dose schedule (2 & 4 months) of Rotarix® (NSW Schedule)\(^1,3\) should be commenced when infants are still in hospital, are clinically stable and are at the appropriate postnatal age (2 months) to commence the National Immunisation Programme \(^3,4\).

Re-administration of the rotavirus vaccine is not recommended if infants regurgitate or posit vaccine after administration\(^1\). There have been no studies regarding the potential harms associated with re dosing\(^6\).

Rotarix® is a live vaccine and rotaviruses can be shed in the stool particularly after the first dose. Studies investigating horizontal transmission have not been performed\(^4\). Although risk of cross infection appears low please follow all standard precautions with handling and disposal of nappies.

Infants living in households with immunocompromised persons can be safely vaccinated\(^1\).

The decision to administer the Rotarix® vaccine outside the recommended age limits for dosing – must be discussed with parents by a Staff Specialist or Neonatal Fellow.

Catch up vaccination with Rotarix® is not recommended\(^1,4\).

3.7.2 Intramuscular immunisation

Give baby oral sucrose and a pacifier to suck for pain relief (sucrose works synergistically with sucking) approximately 2 minutes before injection as per sucrose protocol \(^5-8\).

Cleanse skin with alcohol. Allow to dry before administering vaccine to eliminate the risk of inactivation.

In preterm infants use a 25 gauge needle (16mm in length) and for term infants use a 25 or 23 gauge needle 16mm in length\(^1\) (page 72). Ensure the immunisation is given into the muscle and not given subcutaneously.

The vastus lateralis muscle in the anterolateral thigh is the recommended site for IM vaccination in infants <12 months of age, due to its larger muscle size. Do NOT inject into the anterior aspect of the thigh where neurovascular structures can be damaged – see diagram below.

Use the upper middle third of the vastus lateralis. The skin should be stretched flat for the larger baby and needle angled at 90° to the skin. This reduces tissue resistance and injection pain. Inject slowly (over 5 seconds) into the anterolateral thigh\(^1\) (page 79).
For the extremely preterm infant receiving hepatitis B vaccination at birth you may need to bunch the muscle to ensure the injection is intramuscular.

If the process of administration of a vaccine given parenterally (IM) is interrupted (e.g. by syringe–needle disconnection) and most of the dose has not been administered, the whole dose should be repeated as soon as practicable.

Document site of each injection in infant’s notes eg (R) thigh Infanrix hexa and (L) thigh Prevenar

**Diagram 1** - Anatomical markers used to identify the vastus lateralis injection site (X) on the anterolateral thigh.

Identify the following anatomical markers: the upper marker is the midpoint between the anterior superior iliac spine and the pubic tubercle, and the lower marker is the upper part of the patella.

Draw an imaginary line between the two markers down the front of the thigh. The correct site for IM vaccination is lateral to the midpoint of this line, in the outer (anterolateral) aspect. Do NOT inject into the anterior aspect of the thigh where neurovascular structures can be damaged (page 79).
3.8 Documentation

Document administration of vaccination in the Blue Book including the type of vaccination, batch number, name of person providing, date given and date next due.

Document the vial, batch number and expiry on the medication chart and injection site/s in progress notes.

The Newborn Family Support Team (NFST) will place Parent Information Sheet in the Blue Book of all infants less than 32 weeks who receive Rotarix® and who also require an additional hepatitis B vaccination at 12 months.

Infants < 28 weeks will require Prevenar (13vPCV) at 12 months – see Appendix: Additional vaccine requirements.

Fill out the Australian Children's Immunisation Register (ACIR) encounter form* for all but the H-B-VAX II given at birth, which is considered routine (forms are kept in Special Care Nursery).

* Vaccination details must be submitted to the Australian Commonwealth Immunisation Registry (ACIR) using the purple and orange encounter forms so that the child's immunisation history can be maintained. Forms can be ordered toll-free on 1800 653809. Completed forms are faxed to the ACIR by the ward clerk.

3.9 Reporting an Adverse Event

Pharmacy will report significant adverse events (called ‘adverse events following immunisation’ or ‘AEFI’) to the Adverse Drug Reactions Advisory Committee. Page the Newborn Care pharmacist on 81054 who will then provide the appropriate paperwork and enter details into the database.

3.10 Opportunistic immunisation at outpatient appointments

Assess infant for any risk factors and discuss benefits of immunisation with parents.

Notify staff specialist or neonatal fellow to prescribe immunisation (nurse practitioners cannot prescribe for outpatients).

Obtain parental consent and document same in inpatient / outpatient records and Blue Book.

Advise parents when next immunisation is due and the importance of same.

Administer sucrose as per protocols 5-8, immunise baby and observe him /her in a designated area for 15 minutes after vaccination.

Ensure parent/guardian is aware of signs of adverse events and how to obtain assistance.

Provide parents with a contact phone number for Newborn Care.
3.11 Additional vaccine requirements for infants < 32 weeks

3.11.1 Hepatitis B
As preterm babies are thought to not seroconvert the hepatitis B vaccine as well as term babies, the NHMRC recommends an additional vaccination at 12 months of age for preterm infants < 32 weeks gestation, that is at birth, 2, 4, 6, and 12 months. Please flag this in the Blue Book by inserting the relevant sticker and inform the parents.

3.11.2 Pneumococcal vaccine
'Medical at risk children' will require an additional dose of Prevenar at 12 months and again at 4 years of age – see appendix. Please flag this in the Blue Book by inserting the relevant sticker and inform the parents.

3.12 Additional Information

It may be necessary to reassure parents that immunisation is not associated with SIDS, cancer, inflammatory bowel disease, chronic fatigue syndrome, MS, autism, allergies or auto-immune disease. Preterm infants do not have a higher incidence of adverse events but apnoea has been observed in some infants and therefore we monitor for 24 hours post immunisation.

4. Performance Measures
All immunisations (except routine Hepatitis B vaccination at birth) are submitted to the Australian Commonwealth Immunisation Registry (ACIR).

Documentation of immunisation should be confirmed by sighting the medical record and Personal Health Record (Blue Book) of each infant during the discharge planning process.
5. References and links


6. APPENDIX - INFANTS WITH SPECIAL VACCINATION REQUIREMENTS

PNEUMOCOCCAL VACCINATION

*Infants with the following disease/conditions require booster pneumococcal vaccination on their immunisation schedule at 12 months and 4 years. These doses are additional to routine scheduled pneumococcal vaccination at 2, 4 & 6 months of age.*

**Category A:** Conditions associated with the **highest** risk of invasive pneumococcal disease (IPD)

1. Congenital immune deficiency including symptomatic IgG subclass or isolated IgA deficiency (but children who require monthly immunoglobulin infusion are unlikely to benefit from vaccination)
2. Immunosuppressive therapy (including corticosteroid therapy equivalent to greater than or equal to 2mg/kg per day of prednisolone or equivalent for more than one week) or radiation therapy, where there is sufficient immune reconstitution for vaccine response to be expected
3. Compromised splenic function due to sickle haemoglobinopathies, or congenital or acquired asplenia
4. Haematological & other malignancies
5. HIV infection (including AIDS)
6. Renal failure, or relapsing or persistent nephrotic syndrome
7. Intracranial shunts
8. Cochlear implants

**Category B:** Conditions associated with an **increased** risk of IPD

9. Chronic cardiac disease associated with cyanosis or cardiac failure
10. All premature infants with chronic lung disease
11. All infants born at less than 28 weeks gestation
12. Cystic fibrosis
13. Insulin-dependent diabetes mellitus


HEPATITIS B VACCINATION

Preterm babies do not respond as well to hepatitis B vaccine as term babies. Thus, for babies under 32 weeks’ gestation or < 2000g birth weight, it is recommended to:

Give a booster at 12 months of age with the 12 months vaccination schedule.