Immunisation for the low birth weight and/or preterm infant

The Immunisation Advisory Centre

Executive summary

» Premature and low birth weight infants are at greater risk of increased mortality and morbidity from vaccine preventable diseases.
» Except for BCG, immunisations should be given according to the National Immunisation Schedule at the appropriate chronological age.
» Do not adjust age for preterm birth, i.e. National Immunisation Schedule vaccines start at 6 weeks of age from the date of birth.
» The usual vaccine dosage should be used.

Vaccine immunogenicity	» Inferior immune response to some vaccines although evidence suggests the response is still protective.
Vaccine safety	» Immunisation in these infants is safe and effective. However, post-immunisation apnoea with or without associated bradycardia up to 48 hours post-immunisation may be increased in some groups.
Apnoea	» Factors possibly associated with an increased incidence of post-immunisation apnoea: » Apnoea within the 24-hour period before immunisation. » More severe illness at birth. » Chronological age less than 67 days and/or earlier gestational age in infants with a birth weight of less than 1500g. » An apnoeic episode following the first immunisation event.
Apnoea monitoring	» Consider after the first immunisation event. » Consider after subsequent immunisation events when an infant has experienced apnoea after their first immunisation event. » No long-term sequelae have been associated with post immunisation apnoeic events. » Immunisation should not be withheld or delayed.
Vaccine administration	» Preferred site for intramuscular immunisation is the vastus lateralis. » A 23–25 gauge x 16mm needle inserted at a 90° angle to the skin is usually adequate.
Targeted immunisation or cocooning	» Immunisation of close contacts » Some close contacts may be eligible to receive a funded pertussis booster immunisation. Others can purchase the vaccine through their family doctor or some community pharmacies. » Influenza immunisation is not funded on the basis of being a close contact. The vaccine can be purchased through their family doctor or some community pharmacies.
Recommendations for individual vaccines	
Infants born to hepatitis B carrier mothers	» Give hepatitis B immunoglobulin (HBIG) and a hepatitis B immunisation* within 12 hours of birth regardless of birth weight, followed by: » Three doses of hepatitis B containing vaccine (DTaP-IPV-HepB/Hib [Infanrix®-hexa]) beginning at 6 weeks of age, regardless of birth weight. Serology testing for hepatitis B infection (HBsAg) and immunity (antiHBs) is recommended at 9 months of age.
*HBvaxPRO 5mcg is available until its expiry date of 10 November 2020. Engerix-B® 10mcg/0.5mL is expected to arrive in November 2020. If neither HBvaxPRO 5mcg nor Engerix-B 10mcg is available, Engerix-B 20mcg/mL will need to be used. There are no safety concerns.	
Infants of non-hepatitis B carrier mothers	» Three doses of hepatitis B containing vaccine (DTaP-IPV-HepB/Hib [Infanrix-hexa]) beginning at 6 weeks of age, regardless of birth weight.
Tuberculosis (BCG)	» Eligible infants born at 34 weeks gestation or later can receive the BCG vaccine soon after birth. » Eligible infants born before 34 weeks gestation should have their BCG delayed until 34 weeks gestational age.
Diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b (Hib)	» Three doses beginning at 6 weeks of age. » Administer as DTaP-IPV-HepB/Hib (Infanrix-hexa).
Pneumococcal disease	» Infants who are <u>not</u> eligible for the high-risk pneumococcal immunisation programme » Give the routine National Immunisation Schedule pneumococcal conjugate vaccine (PCV13) at 6 weeks, 5 months and 12 months of age. » Infants who are eligible for the high-risk pneumococcal immunisation programme » PCV13/Prevenar 13® at 6 weeks, 3 months, 5 months and 12 months of age. » Two 23-valent pneumococcal polysaccharide vaccine doses (23PPV/Pneumovax®23) are recommended and funded if the infant continues to be at high-risk of pneumococcal disease, the first at 2 years of age and the second five years after the first.
Rotavirus	» Two doses of rotavirus vaccine (Rotarix®) beginning at 6 weeks of age. » Infants in hospital at 6 weeks of age should receive the first Rotarix dose on time. » No increase in nosocomial rotavirus transmission within neonatal intensive care units. » Standard infection control precautions should be maintained.
Influenza	» Influenza vaccine annually from 6 months of age. » Preterm birth alone does not meet the eligibility criteria for receipt of funded vaccine. » Two doses of vaccine administered one month apart in the first year, then one dose annually in each subsequent year.

Immunisation for the low birth weight and/or preterm infant

The Immunisation Advisory Centre

Young infants are especially vulnerable to a number of vaccine preventable diseases, particularly pertussis (whooping cough), *Haemophilus influenzae* type b (Hib) disease, pneumococcal disease and influenza. Preterm and low birth weight infants have an even higher risk than full term infants of developing serious complications from vaccine preventable diseases.

Preterm birth is defined as birth before 37 weeks gestation and low birth weight refers to infants born weighing less than 2500 grams. Except for the BCG vaccine, gestational age and birth weight are not limiting factors when deciding whether a clinically stable preterm infant is to be immunised at the appropriate chronological age, following the same immunisation schedule as infants born full-term. The recommended dose of each vaccine should be used, doses should not be divided.

Passive immunity in preterm infants

Transplacental transfer of maternal immunoglobulin G (IgG) that can protect an infant against some vaccine preventable diseases is affected by a range of factors including the mother's past exposure to the disease and immunisation history, antibody half-life, and the infant's gestational age. Around 28–32 weeks gestation, the levels of maternal IgG in the infant are only around half of the maternal levels, compared with higher than maternal IgG levels in term infants. Furthermore, IgG wanes more rapidly rendering preterm infants at increased and earlier risk for vaccine preventable diseases.

Vaccine immunogenicity

Preterm infants have an inferior immune response to some vaccines although evidence suggests that the response is still adequate for protection.

Vaccine safety

Vaccines in preterm and/or low birth weight infants have excellent safety profiles, comparable to those in full term infants, except for a possible increase in apnoea with or without associated bradycardia up to 48 hours post-immunisation.

Apnoea

Factors that have been identified as possibly being associated with an increased incidence of post-immunisation apnoea include apnoea within the 24 hour period before immunisation, more severe illness at birth, chronological age less than 67 days, and/or earlier gestational age in infants with a birth weight of less than 1500g. Although apnoeic episodes are not necessarily causally associated with immunisation, an apnoeic episode following the first immunisation event is a significant risk factor for an apnoeic episode following the second immunisation event. No long-term sequelae have been associated with post immunisation apnoeic events.

Apnoea monitoring

Apnoea monitoring of preterm and/or low birth weight infants, particularly those with a history of respiratory immaturity, should be considered after the first immunisation event. When an infant has experienced apnoea after their first immunisation event, apnoea monitoring (for both medical reasons and to maintain parental confidence in immunisation) should be considered after subsequent immunisation events. Immunisation should not be withheld or delayed.

Vaccine administration

The preferred site for intramuscular immunisation in preterm or low birth weight infants is the same as for full term infants, the vastus lateralis. A 23–25 gauge x 16mm needle inserted at a 90° angle to the skin is usually adequate.

Targeted immunisation or cocooning

Research suggests that most infants acquire diseases such as whooping cough and influenza from family members. "Cocooning" or "targeted immunisation" involves ensuring siblings are up to date with their immunisations, and immunising the infant's close contacts (parents, grandparents and carers) to reduce the risk of disease exposure for the infant. Important vaccines to consider include pertussis-containing vaccines and influenza vaccines.

Estimates of pertussis vaccine efficacy in adolescents and adults vary from 51–92%. In those who develop immunity, protection against disease is highest over the first year after immunisation and wanes rapidly over 4–6 years. Reducing the risk of close contacts having active disease is beneficial for infants.

However, pertussis carriage and transmission of bacteria from asymptomatic contacts may be possible. Studies measuring the "cocoon" effect from targeted pertussis immunisation report 'no benefit' to around a 50% reduction in the pertussis disease risk in infants aged under 4 months.

Any adult with a cough needs to have pertussis excluded before spending time with infants even if they have received a pertussis booster immunisation. Despite a relatively rapid loss of protection in vaccine responders, booster doses of pertussis-containing vaccine are recommended no more frequently than 10-yearly for non-pregnant adolescents and adults.

One pertussis booster vaccination (Tdap/Boostrix) dose is free for parents or primary caregivers of an infant admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than three days and whose mother did not receive maternal Tdap vaccination at least 14 days before birth.

For infants born before 32 weeks gestation and whose mother received maternal Tdap vaccination more than 14 days before birth, one pertussis booster vaccination is also recommended, but not funded, for parents or primary caregivers as the level of transplacental maternal antibodies in these infants is only around half of the maternal circulating antibody level.

The pertussis containing Tdap (Boostrix) vaccine is also funded for adults who need to complete a primary course of tetanus/diphtheria vaccines, some adults aged 45 years as a booster vaccination, and adults aged 65 years as a booster vaccination.

Influenza vaccine efficacy is dependent on the age, immune status and health of the recipient, as well as the match between the vaccine influenza strains and strains circulating in the community. Influenza vaccines are not funded by the Ministry of Health based on the person being a close contact but can be purchased through the person's general practice or some community pharmacies. Influenza vaccination for healthcare workers is usually funded by their employer.

Recommendations for individual vaccines

Hepatitis B

Infants born to hepatitis B carrier mothers

Infants born to HBsAg-positive (hepatitis B surface antigen-positive) mothers require hepatitis B immunoglobulin (HBIG) and a hepatitis B immunisation within 12 hours of birth. Without hepatitis B immunoprophylaxis these infants have up to a 50% risk of acquiring the disease perinatally and more than 90% likelihood of progressing to chronic hepatitis if they do acquire the disease with the associated lifelong risk of developing liver cirrhosis and cancer.

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Immunisation for the low birth weight and/or preterm infant

The Immunisation Advisory Centre

Infants born to hepatitis B carrier mothers continued

When the mother is also HBeAg-positive (a marker for high viral replication) at the time of delivery, the risk of perinatal hepatitis B infection increases to 90%. However, routine testing for HBeAg is not done because infection can still be transmitted when the HBeAg is non-detectable.

HBIG is expected to be effective in very low birth weight infants. In a small study 10 infants, all weighing less than 1750g when born to hepatitis B carrier mothers, received HBIG at birth but no hepatitis B immunisation until 11–59 days old. No infants became hepatitis B surface antigen positive.

Some studies suggest that infants weighing less than 2000g at birth have decreased seroconversion to hepatitis B vaccine. Corticosteroid use and hyperbilirubinaemia may also reduce the immune response to hepatitis B vaccine. However, these are not reasons to delay the birth hepatitis B immunisation. By 4 weeks of age all infants, independent of gestational age and birth weight, are expected to respond to the hepatitis B vaccine and develop protection against the disease.

In New Zealand, a complete course of three hepatitis B vaccine doses are administered from 6 weeks of age irrespective of whether the infant had a birth dose of vaccine. Serology testing for hepatitis B infection (HBsAg) and immunity (antiHBs) is recommended at 9 months of age for all infants born to hepatitis B carrier mothers.

Infants born to mothers whose hepatitis B carrier status is not known

Infants of mothers whose HBsAg status is unknown at the time of delivery require hepatitis B immunisation at birth while waiting for the results of urgent HBsAg testing on the mother. If mother is found to be HBsAg positive, HBIG will also be required regardless of their birth weight.

Infants of non-hepatitis B carrier mothers

Infants born to hepatitis B negative (HBsAg negative) mothers prematurely and/or weighing less than 2000g are expected to be adequately protected against hepatitis B after three doses of vaccine beginning at 6 weeks of age.

BCG

It is recommended that the BCG immunisation is administered soon after birth to infants who are at increased risk of tuberculosis and meet the eligibility criteria described in table 1 on the following page.

Studies measuring the preterm and/or low birth weight infant's response to the BCG immunisation have used BCG scar, Mantoux response and/or the lymphocyte migration inhibition test to assess the infant's response. Some data indicates that administering the BCG immunisation at a gestational age of 34 weeks or later provides a good immune response. Other data suggests that the BCG immunisation can be given as early as a gestational age or 31 weeks. As these methods are now known to provide false negative indicators of immune response, and in the absence of recent data using modern and more accurate tests, a conservative approach to administering the BCG to preterm and/or low birth weight infants is advised.

Infants born at 34 weeks gestation or later can receive the vaccine soon after birth. Infants born before 34 weeks gestation should have their BCG delayed until they reach a gestational age of 34 weeks.

Diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b (Hib)

Diphtheria and tetanus toxoid vaccines are highly immunogenic in preterm infants. The immune response to the acellular pertussis vaccine in preterm infants has been shown to be lower than in those born at full term but has been shown to be efficacious when administered to preterm infants.

Pneumococcal

The 13-valent pneumococcal conjugate (PCV13/Prevenar 13) vaccine has been shown to be immunogenic in infants born before 37 weeks gestation and infants born at less than 2500g, but earlier gestational age and/or extremely low birth weight may influence the magnitude of antibody response and duration of protection following the primary vaccine course.

Timely administration of the booster dose in the second year of life is recommended. PCV13 has been shown to be safe and generally well tolerated in preterm and/or low birth weight infants.

Eligibility for the high-risk pneumococcal immunisation programme for infants and children aged under 5 years is outlined in table 2 on the following page.

Infants who are not eligible for the high-risk pneumococcal immunisation programme are recommended to receive the routine National Immunisation Schedule pneumococcal conjugate vaccine (PCV13) at ages 6 weeks, 5 months and 12 months.

Infants who are eligible for the high-risk of pneumococcal immunisation programme are recommended to receive PCV13/Prevenar 13 at ages 6 weeks, 3 months, 5 months and 12 months. Two 23-valent pneumococcal polysaccharide vaccine doses (23PPV/ Pneumovax23) are recommended and funded if the infant continues to be at high-risk of pneumococcal disease, the first at 2 years of age and the second five years after the first.

Rotavirus

Rotarix has been shown to be safe and efficacious when given to preterm infants born between 27–36 weeks gestation following the same schedule as full-term infants. Adverse events and vaccine immunogenicity were comparable with the preterm cohort receiving the placebo and term infants in an earlier Rotarix safety and immunogenicity study.

The weakened (attenuated) rotavirus from Rotarix may be found in stools for up to 28 days after the first immunisation and up to 15 days after the second. However, no increase in nosocomial rotavirus transmission within neonatal intensive care units has been observed. Standard infection control precautions should be maintained.

Preterm infants are at increased risk for hospitalisation from rotavirus during their early years of life. Rotarix can be administered to medically stable, hospitalised infants at 6 weeks of age. The vaccine has been shown to be well-tolerated in these infants, and no increase in nosocomial rotavirus transmission was observed within the neonatal intensive care unit (NICU).

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Immunisation for the low birth weight and/or preterm infant

The Immunisation Advisory Centre

Influenza

Annual influenza vaccine is recommended for all preterm infants from 6 months of age. However, preterm birth alone does not meet the eligibility criteria for receipt of funded vaccine. All infants and children aged under 9 years receiving influenza vaccine for the first time require two doses of vaccine administered one month apart, then one dose annually in each subsequent year

Table 1: Neonatal BCG eligibility criteria

Neonatal BCG is recommended and funded for infants at increased risk of TB, defined as those who:

- will be living in a house or family/whānau with a person with either current TB or a history of TB
- have one or both parents or household members or carers who within the last five years lived for a period of six months or longer in countries with a TB rate ≥40 per 100,000*
- during their first five years will be living for three months or longer in a country with a TB rate ≥40 per 100,000.*

*A list of high-incidence countries and their TB rates is available in Appendix 8 in the *Immunisation Handbook*.

Table 2: Eligibility for the high-risk pneumococcal immunisation programme for infants and children aged under 5 years

» Cardiac disease with cyanosis or failure	» HIV-positive
» Cerebrospinal fluid leak	» Immunosuppressive therapy
» Chronic pulmonary disease, including asthma treated with high-dose corticosteroid therapy	» Intracranial shunt
» Cochlear implant	» Nephrotic syndrome
» Corticosteroid therapy for more than two weeks and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater	» Pre-or post-splenectomy
	» Pre-term infant born before 28 weeks gestation
	» Primary immune deficiency
	» Post-haematopoietic stem cell transplantation
» Diabetes	» Post-solid organ transplantation
» Down syndrome	» Radiation therapy
» Functional asplenia	» Renal failure

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