CLINICAL PRACTICE GUIDELINE

Vaccinations

This document should be read in conjunction with this **Disclaimer**

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Vaccine preparation

- Ensure that the minimum / maximum thermometer displays temperatures within the +2°C to +8°C range before removing the vaccine from the refrigerator.
- Ensure that the correct vaccine (check against the prescription) is taken from the refrigerator and that it is within expiry date.
- Check that there is no particulate matter or colour change in the vaccine.
- Prepare the appropriate injection equipment for the vaccine to be administered.
- Do not push small air bubbles through the needle for injection. In the rare
 instance of a large air bubble in a pre-filled syringe, first draw back on the
 needle to ensure no vaccine is expelled along with the air, and then expel the
 air through the needle, taking care not to prime the needle with any of the
 vaccine, as this can lead to increased local reaction.
- For more details on preparation, administration (injection sites and techniques) or procedures after vaccination, see the Australian Immunisation Handbook: <u>Vaccination Procedures</u>.
 Reference¹
- See also Public Health Take 5 on <u>Managing a Cold Chain Breach</u> (available to WA Health staff through Healthpoint)

Adult

Antenatal vaccination protocol: Pertussis and influenza (Adult)

Key points

- 1. Check beforehand that the vaccination has not already been given by another service.
- 2. The pertussis vaccine and influenza vaccine are not live vaccines.
- 3. Vaccination with influenza and dTpa is recommended with each pregnancy to provide maximum protection to every infant; this includes pregnancies which are closely spaced (e.g. < 2 years).
- 4. The vaccines may only be administered by:
 - A Medical Practitioner
 - ➤ A Registered Nurse or Midwife (includes PG midwifery students but excludes undergraduate midwifery or nursing students)
- 5. A Registered Nurse / Midwife may administer the vaccine at KEMH with a written medication order provided the consent form has been completed and is present with the medical notes.
- Registered Nurses / Midwives who meet the requirements of the relevant Chief Executive Officer of Health Structured Administration and Supply Arrangements (<u>SASA</u>) may administer these vaccines at KEMH without a formal written medical order. See <u>Registered Nurses – vaccination (Word 91KB)</u> and <u>Midwives – vaccination (Word 90KB)</u> for requirements.
- 7. The person administering the vaccines(s) must complete the administration section of the consent form following administration. The original must be filed in the woman's medical notes.
- 8. Read Department of Health WA: <u>OD: 0600/15 Influenza and Pertussis Vaccinations for Pregnant Women</u> for background information.
- 9. **Influenza**: Influenza vaccination can be administered at any time during pregnancy. See Department of Health WA:
 - <u>Immunisation Schedule</u> (external website)
 - Influenza Immunisation Program (external website).

10. Pertussis:

• The recommendation for pertussis vaccination has been updated (May 2019). Pertussis vaccination will be offered to all antenatal women, (mid 2nd trimester to early 3rd trimester) with optimal timing 20-32 weeks gestation.¹

- 20-32 weeks gestation is the optimal time for administration of pertussis vaccination (diphtheria, tetanus and pertussis) dTPa, however if not vaccinated during this time, they should receive the vaccine as soon as possible and at any time during the third trimester up to birth. If given within two weeks of birth, the newborn may not be adequately protected.¹
- Women who have a preterm birth prior to receiving the pertussis vaccine i.e. <28-32 weeks should be offered pertussis vaccination prior to postnatal discharge.
- If women receive the vaccine earlier than 20 weeks, they do not need a repeat dose in the same pregnancy.¹
- Partners and family members are **not** eligible to participate in the WA
 Health Pertussis in Pregnancy Programme but should be advised to
 consider vaccination via their nominated healthcare provider.

Contraindications

- Pertussis: Previous life threatening allergic reaction after any pertussis, tetanus or diphtheria containing vaccine or severe allergy to any part of the vaccine.
- Influenza: Previous life threatening allergic reaction after a dose of influenza vaccine or severe allergy to any part of the vaccine.

Discussion and informed consent

- Discussion about Pertussis and Influenza vaccination should occur as part of routine antenatal care late in the second trimester and during the early third trimester.
- All women must be provided with a copy of the Pertussis Vaccine in Pregnancy (ViP) and the Influenza ViP leaflets.
- The risks and benefits of vaccination must be discussed.
- If after discussion, the woman choses to participate in either or both of the programmes she must complete the 'Antenatal Vaccination Authorisation and Consent Form' prior to the vaccines' administration
- See also Department of Health WA: Consent Process For Vaccination

Administration

- See Pharmacy guidelines: Pertussis Vaccine and Medication Administration
- Prior to administration the two people checking and administering the vaccine(s) must ensure the woman has completed and signed the "Antenatal Vaccination Consent Form"
- Refer to section: <u>Vaccine Preparation</u> above

- The procedure for checking and administering the vaccine(s) shall be as per clinical guideline Schedule 4 Prescription Only Medication Administration
- The vaccine(s) must be administered intramuscularly into the deltoid muscle
 of either arm. It must not be administered into the buttocks or thigh.
- If two vaccines are to be given, they must be administered as separate injections. If required, they can be given in the same arm separated by 2.5cm from the initial injection site. The location of each vaccine administration is to be documented on immunisation sticker and consent form.
- IM administration should be given with care in women suffering from coagulation disorders due to the risk of haemorrhage. In these circumstances administration by deep subcutaneous injection may be considered, although there is a risk of increased local reactions.
- Following administration the person administering the vaccine(s) must complete the Antenatal Vaccination Authorisation and Consent form with the details of the vaccines used and the form scanned and emailed to the CDCD at antenatal.immunisation@health.wa.gov.au.
- A KEMH antenatal vaccination sticker must also be completed and placed in the medical notes on the MR004 Special Instructions Sheet.
- Documentation:
 - ➤ The vaccine vials/ pre-filled syringe each have 2 identification stickers which may be used in completing the documentation.
 - > Staff vaccinating under the relevant SASA are required to document immunisations on the Australian Immunisation Register (AIR).
- If following receipt of the information sheets and discussion, a woman declines vaccination, a KEMH 'Declined Antenatal Vaccination' sticker must be completed and placed on the MR004 Special Instruction sheet in the medical notes.

Post vaccination care

The vaccinated person should be advised to remain in the vicinity for a
minimum of 15 minutes after the vaccination. The area should be close
enough so that the vaccinated person can be observed and medical treatment
provided rapidly if needed.

Management of anaphylaxis

Manage as per Clinical Guidelines:

- Anaesthetics: <u>Anaphylaxis</u> (access for WA Health employees through Healthpoint)
- Obstetrics & Gynaecology: <u>Clinical Deterioration</u>

See also NMHS, Metropolitan Communicable Disease Control: <u>Anaphylaxis: A</u> Guide for Healthcare Workers Influenza Program Vaccinators (2019)

Measles, mumps & rubella (MMR) vaccine administration (Adult)

Aims

- The prevention of congenital malformations due to rubella infection in a subsequent pregnancy.
- To inform clinical staff of the <u>key points</u>, <u>procedure</u>, <u>contraindications</u>, <u>precautions</u> and <u>side effects</u> relevant to administration of the measles, mumps and rubella (MMR) vaccine.

Background

Maternal rubella infection in the first trimester of pregnancy can result in fetal infection and malformations in up to 90% of affected pregnancies. Rubella outbreaks in populations that are vaccinated against rubella are rare. Fetal damage after 16 weeks is rare but has been reported up to 20 weeks gestation. The number of cases of congenital rubella syndrome (CRS) has fallen rapidly since rubella vaccine licensure in Australia. Maternal rubella infection can result in severe congenital abnormalities and fetal demise.

Key points

- 1. Rubella immunity should be determined for every pregnancy and testing should be offered at the first antenatal appointment. If non immune, women can then be offered vaccination after the birth to provide protection against rubella infection and related fetal malformations in future pregnancies.²
- 2. Every effort should be made to identify non-pregnant, non-immune women of child bearing age and provide the MMR vaccine.¹
- 3. The following women are more likely to be non-immune/ seronegative to rubella¹:
 - Aboriginal and Torres Strait Islander women living in rural or remote regions²
 - Women born overseas (particularly in Asia, Pacific Islands, sub-Saharan Africa and South America) who have entered Australia after the age of routine vaccination are twice as likely to be non-immune than Australian-born women²
 - Non-English speaking women
 - Women over the age of 35 (possibly due to declining immunity)²
 - Australian-born Muslim women.¹

- 4. Women found to be seronegative on antenatal rubella immunity testing should be offered the MMR vaccine after giving birth and before discharge¹ from KEMH.
- 5. Adult MMR is on the <u>WA vaccination schedule</u> (PDF 129KB) where <2 doses MMR received.
- 6. Adult rubella vaccination is only available as the MMR, as there is no monovalent rubella vaccine in Australia. MMR with varicella (MMRV) is not appropriate for women aged >14 years and is only used as a single dose at 18 months of age.¹
- 7. Co-administration with other injections
 - Rh (D) immunoglobulin (anti-D) does not interfere with the antibody response to the vaccine. If anti-D is also required, the two may be given at the same time in different sites with separate syringes, or at any time in relation to each other.¹
 - MMR vaccine can be given simultaneously with other live attenuated parenteral vaccines (e.g. varicella vaccine) and other inactivated vaccines using separate syringes and injecting sites. Vaccines must not be mixed together in a single syringe. If live vaccines are not given simultaneously they should be given at least 4 weeks apart.¹
- 8. Breast feeding is not a contraindication to rubella vaccine.^{3, 4} The rubella virus may be secreted in breast milk and transmitted to neonates, however the attenuated virus is well tolerated⁴, with mild or absent symptoms in situations where infection has occurred.¹
- There is no risk to pregnant women from contact with recently vaccinated individuals with MMR vaccine. The vaccine virus is not transmitted from vaccinees to susceptible contacts.¹
- 10. If the woman has become pregnant within 28 days of a MMR vaccine, inform her that the fetus is unlikely to have been affected by the vaccine. 1, 2

Who should not have the vaccine?

Before being vaccinated, ask the woman if they:

- aren't feeling well (for example you have a fever)
- have any severe allergies (such as antibiotics, latex, gelatine)
- are pregnant or plan to be pregnant in the next 2 months
- have received another live vaccination in the last month
- have received blood, blood products or immunoglobulin in the last 3 months
- have a disease (for example HIV/AIDS or cancer) or having treatment that lowers immunity.
 - Ref: http://healthywa.wa.gov.au/Articles/J_M/Measles-mumps-rubella-MMR-vaccine

Procedure

- 1. Ensure the woman understands the reasons for vaccination as soon as she is no longer pregnant⁴, and gain her informed consent prior to administration.
- 2. Confirm by sighting pathology results that the woman's rubella immunity level is low, and check for allergies and contraindications prior to administration.
- 3. Refer to section: Vaccine Preparation above
- 4. If the skin is not visibly clean, wipe the site with an alcohol wipe and allow to **dry** (alcohol can inactivate the viruses in the vaccine).⁵
 - Whether administration is intramuscular (IM) and / or subcutaneous (SC) is dependent on the individual MMR brand, see vaccine vial and administer accordingly.¹
- 5. After administration, document on the woman's medication chart (MR810). In the medical record document the following:
 - Date and time of administration, and
 - Manufacturer and batch number.
- 6. Provide the woman with the KEMH MMR vaccination letter. All women receiving the MMR vaccine must be counselled about the need to avoid becoming pregnant for 28 days after vaccination¹. Women who have received the MMR vaccination must be advised that they should be tested for rubella immunity 6-8 weeks after vaccination.^{1, 3} Women who are non-immune after vaccination are recommended to receive a second dose¹ Levels that remain low after a second documented vaccination are unlikely to increase with further vaccinations.¹

Contraindications¹

- Allergy to vaccine components:
 - > Anaphylaxis following a previous dose of rubella, MMR or MMRV or
 - Anaphylaxis following any vaccine component.⁵
- People who are immunocompromised.^{3, 5} This includes women:
 - who are significantly immunocompromised because of a medical condition(s)
 - > receiving high dose systemic immunosuppressive therapy, such as chemotherapy, radiation therapy or oral corticosteroids
 - > See section <u>Vaccination for People who are Immunocompromised</u> in the Immunisation Handbook for more details
- Pregnancy⁵; pregnancy should be avoided for 28 days after receiving the live MMR vaccine.⁴ If the woman becomes pregnant in this period, she should be counselled by her medical practitioner. No evidence of vaccine induced Congenital Rubella Syndrome has been reported. Based on this evidence the

vaccine cannot be considered teratogenic and termination of pregnancy following inadvertent vaccination is not indicated.

Precautions¹

- Vaccination after receiving immunoglobulin or a blood product
 - A recent blood transfusion with washed red blood cells is not a contraindication to MMR vaccine
 - ➤ Rubella containing vaccine should **not** be given within **at least 3-11 months** after administration of an immunoglobulin-containing blood product e.g. packed red blood cells, whole blood transfusion, immunoglobulin (except anti-D; see key point 6 above), or other antibody-containing blood products (e.g. plasma or platelet products), because the expected immune response may be impaired, with vaccine failure due to passively acquired MMR antibodies.⁵
 - More specific guidance of vaccine deferral periods depending on the type of blood products received by the woman is available in the <u>Australian Immunisation Handbook</u>:
 - <u>Table of Recommended intervals between immunoglobulins or</u> <u>blood products, and MMR, MMR-V or varicella vaccination and</u>
 - Vaccination for people who have recently received normal human immunoglobulin and other blood products.
- Refer to the <u>Australian Immunisation Handbook</u> for advice regarding vaccination in the context of recent or future blood product administration, immunosuppression/compromise, HIV, and corticosteroid therapy.
- Household contacts of people who are immunocompromised can safely receive MMR as it is not transmissible from vaccinated people to others
- People with a history of thrombocytopenia. Thrombocytopenia is a rare adverse event after MMR vaccination.

Side effects of MMR vaccine¹

- Inform women about possible symptoms occurring 5-12 days after vaccination and how to manage the symptoms including using paracetamol for fever.
 - ➤ Note- Paracetamol should not be given for more than 48 hours without seeking medical advice.
- 7-10 days (range 5-12 days) after injection:
 - Fever lasting 2-3 days that may be associated with malaise, faint red rash (not infectious).
 - ➤ An increased risk for febrile seizures of about 1:3000-4000 doses in same time period
- See Immunisation Handbook: <u>Rubella</u>: for adverse events

Neonatal

Hepatitis B vaccine: Neonatal administration

See also Neonatal Postnatal Ward guideline: <u>Maternal Hepatitis B Virus (HBV): Care of the infant born to HBV positive woman</u> and <u>HB Immunoglobulin</u> (in this document) if the neonate is born to a mother who is HBV positive.

Key points

- 1. All neonates should be offered hepatitis B vaccination.
- 2. The birth dose should be given when the neonate is physiologically stable, preferably within 24 hours of birth.¹
- 3. The first birth dose of hepatitis B vaccine should not be delayed beyond 7 days of birth.^{1, 6}
- 4. Neonates (term or preterm) of hepatitis B carrier mothers should be given a birth dose of hepatitis B vaccine (Paediatric) and paediatric dose of hepatitis B immunoglobulin (HBIG) given on the day of birth at the same time but in separate thighs.¹ See next chapter 'Hepatitis B immunoglobulin (HBIG): Neonatal' for details if HBIG is required.
- 5. Refer to "Neonatal Medication Administration" (page 6) 'Competency Requirements' in clinical guideline, Pharmacy, <u>Medication Administration</u> (available to WA Health employees via Healthpoint).

Prior to administering the HBV vaccine

- Check that the MR 216 Consent for Hepatitis B Immunisation form is signed by the mother.
- Ensure the dosage is written up by a doctor on the MR 811 Neonatal Inpatient Medication Chart.
- Check that the identification name bands on the neonate and mother correspond with the consent form and medication chart.

Administration of the HBV vaccine

Refer to section: Vaccine Preparation

Prepare the site

- 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.
- If the site is soiled in any way, clean the site with soap and water.
- If the mother has a known blood borne virus, ensure the limb is cleaned with soap and water prior to vaccination.

- ➤ If HBIG is required for maternal HBV- it to be administered concurrently therefore both limbs are to be cleaned.
- For infants the preferred needle size is 25mm. If using a 25 gauge needle for an IM injection, ensure the vaccine is injected slowly over a count of 5 seconds to avoid injection pain and muscle trauma.

Administration

- Administer sucrose / breastfeed at the time of injection.
- Ensure the neonate does not move during the IM injection. However excessive restraint can increase the neonate's fear and can result in increased muscle tension.
- Pierce the skin at an angle of 90° to the skin so the needle can safely be inserted to the hub. Provided an injection angle of > 70° is used, the needle should reach the muscle layer.
- If you have drawn back on the syringe plunger before injecting a vaccine (which is not considered necessary) and a flash of blood appears in the needle hub, withdraw the needle and select a new site for injection.

Documentation

Record administration on the:

- MR 811 Neonatal Inpatient Medication Chart- place small batch sticker on the dedicated "pharmacy" box of the drug chart.
- Baby's Personal Health Record (purple book) birth details on page 33 and immunisation record card.
- MR 410 Neonatal History.
- MR 425.10 Care of the Well Neonate Chart.

Postnatal education

- Inform the woman of the schedule for hepatitis B immunisation
- Provide information about known side-effects that may occur following vaccination.
 Refer parents to the Vaccination booklet in the back of the purple book.
- Adverse events after vaccination are transient and minor and may include soreness of the injection site. Fever may occur in neonates after immunisation, (0.6-3.7%).¹

Hepatitis B immunoglobulin (HBIG): Neonatal

The section below must be read in conjunction with the Neonatal Postnatal Ward guideline: <u>Maternal Hepatitis B Virus (HBV)</u> which contains background, key points, management and GP follow-up. The section below contains administration details only.

Dosage

The dose of HBIG is 100IU units to be given by intramuscular injection (IMI).1

Prior to administering the immunoglobulin

- Check consent, identification and prepare as per previous section "Prior to administering" neonatal HBV vaccine.
- The order of HBIG is also written by the doctor on the MR 811 Neonatal Inpatient Medication Chart. The midwife telephones the haematology Blood Bank to request the HBIG; then sends or arranges for a **neonatal** identification sticker label to be taken to the lab for HBIG to be dispensed.
- Refer to section: Vaccine Preparation above

Administration of the immunoglobulin

- Follow section above: Hepatitis B Vaccine: Neonatal Administration
- Administration of the HBIG is given at the same time as the first dose of thiomersal-free monovalent hepatitis B vaccine; within 12 hours of birth in a different thigh.¹
- The limbs must be cleaned with soap and water prior to administration.
- Note: If concurrent administration is not able to be done, vaccination should not be delayed beyond 7 days after birth.
- Postnatal Education and Documentation document HBIG as per Neonatal Hepatitis B Vaccine in previous section

See Neonatal Postnatal Ward guideline: <u>Maternal Hepatitis B Virus (HBV): Quick Reference Guide</u> for additional details

References

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Related policies and legislation

Legislation - Commonwealth Family Law Act 1975; Poisons Act 1964

Policies- Government of Western Australia- Department of Health:

- Operational Directive (OD) <u>0657/16</u>: <u>WA Health Consent to Treatment Policy 2016</u>
 (Parental Consent within 4.3.2 Children and young people p.16)
- OD 0600/15 Influenza and Pertussis Vaccinations for Pregnant Women
- OD 0355/11 Vaccine Cold Chain Guidelines
- OD 0237/09 Hepatitis B Vaccination Program
- OD 0388/12 Health Care Worker Immunisation Policy
- Policy Frameworks: Public Health

Reporting adverse reactions: Western Australian Vaccine Safety Surveillance (WAVSS)

Related WNHS policies, procedures and guidelines

Anaesthetics: Anaphylaxis (available to WA Health employees through Healthpoint)

Infection Prevention and Management Policy Manual:

- Hand Hygiene
- Standard Precautions

Neonatology Postnatal Ward guidelines:

- Maternal Hepatitis B Virus (HBV): Care of the infant born to HBV positive women
- Maternal Hepatitis B Virus (HBV): Quick Reference Guide

Obstetrics & Gynaecology:

- Clinical Deterioration
- Pathology & Ultrasound: Ordering by Midwife / Nurse / Nurse Practitioner: Antenatal tests, Ordering

Pharmacy:

- Pertussis Vaccine
- <u>Fridge Medications and Vaccines</u> (access to WA Health employees through Healthpoint)
- <u>Medication Administration</u> (administration and checking procedure by nursing / midwifery staff) (access to WA Health employees through Healthpoint)

Resources

- Australian Government:
 - Immunisation website including resources for:

Consumers:

- Influenza vaccine video and Influenza vaccine brochure
- Whooping cough vaccine video and Whooping cough vaccine brochure

Health care providers

- Clinical advice fact sheet for providers
- Whooping cough vaccine poster
- o Influenza vaccine poster
- National Pregnancy Care Guidelines: Rubella
- Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra. 2018. Retrieved from https://immunisationhandbook.health.gov.au including sections on:
 - Rubella
 - Table of Recommended intervals between immunoglobulins or blood products, and measles-mumps-rubella, measles-mumps-rubella-varicella or varicella vaccination
 - Vaccination for people who have recently received normal human immunoglobulin and other blood products

- E-learning- <u>Australian Immunisation Register education modules</u> [external site] (for Health professionals)
- Government of Western Australia. Department of Health:
 - Consent Process For Vaccination
 - > Immunisation Schedule
 - Immunisation Education webpage (immunisation videos, courses, and online annual influenza updates for health professionals)
 - Public Health: Take 5's- <u>Anaphylaxis: A Guide for Healthcare Workers Influenza</u> <u>Program Vaccinators</u> and <u>Managing a Cold Chain Breach</u> (available to WA Health staff through Healthpoint)
 - ➤ Public Health and Clinical Services. <u>Vaccine Administration Code</u> January 2016
- <u>National vaccine storage guidelines: Strive for 5</u>. 2nd ed. Canberra: Australian Government Department of Health and Ageing, 2018. (last updated April 2018)

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