HIV exposed infant management

Sites where Local Guideline applies
Delivery Suite & post natal wards JHH and Neonatal Intensive Care Unit, JHCH

This Local Guideline applies to:
1. Adults
   Yes
2. Children up to 16 years
   No
3. Neonates – less than 29 days
   Yes

Target audience
All maternity and neonatal clinical staff that provide maternity and newborn care.

Description
Guideline for the management of a HIV exposed infant

Keywords
baby, HIV, neonate, maternity, newborn, Zidovudine, JHCH, NICU

Document registration number
JHCH_NICU_11.02

Replaces existing document?
No

Related Legislation, Australian Standard, NSW Ministry of Health Policy Directive or Guideline, National Safety and Quality Health Service Standard (NSQHSS) and/or other, HNE Health Document, Professional Guideline, Code of Practice or Ethics:
- NSW Health Policy Directive 2014_036 Clinical Procedure Safety
- Australian Paediatric Surveillance Unit Study Protocol
- NSW HIV Strategy 2016-2020
  Australian ANC Guidelines Module 1

Prerequisites (if required)
N/A

Local Guideline note
This document reflects what is currently regarded as safe and appropriate practice. The guideline section does not replace the need for the application of clinical judgment in respect to each individual patient but the procedure/s require mandatory compliance. If staff believe that the procedure/s should not apply in a particular clinical situation they must seek advice from their unit manager/delegate and document the variance in the patients health record.

Position responsible for the Local Guideline and authorised by
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This document contains advice on therapeutics
Yes

Approval gained from Local Quality Use of Medicines Committee on Dec 2015

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23/02/2019
RISK STATEMENT

This local guideline has been developed to provide guidance to clinical staff in delivery suite, NICU and the Post natal ward to assist in the management of an infant that is exposed to HIV and ensures that the risks of harm to infants, family and staff during the admission are identified and managed.

Any unplanned event resulting in, or with the potential for injury, damage or loss to infants/staff/family as a result of this procedure must be reported through the Incident Information management System and managed in accordance with the Ministry of Health Policy Directive: Incident management PD2007_061. This would include unintended injury that results in disability, death or prolonged hospital stay.

Risk Category: Clinical Care & Patient Safety

GLOSSARY

<table>
<thead>
<tr>
<th>Acronym or Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARV</td>
<td>Anti-retro viral</td>
</tr>
<tr>
<td>AZT</td>
<td>Zidovudine</td>
</tr>
<tr>
<td>CD4</td>
<td>CD4 is a co-receptor that assists the T cell receptor (TCR) in communicating with an antigen-presenting cell. HIV-1 uses CD4 to gain entry into host T-cells</td>
</tr>
<tr>
<td>HAART</td>
<td>Highly Active antiretroviral therapy</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>HNELHD</td>
<td>Hunter New England Local Health District</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase Chain Reaction - is used to amplify a specific region of a DNA strand</td>
</tr>
<tr>
<td>PPE</td>
<td>Personal protective equipment</td>
</tr>
<tr>
<td>Viral DNA</td>
<td>virus that has the molecule Deoxyribonucleic acid as its genetic material</td>
</tr>
</tbody>
</table>

OUTCOMES

1. For pregnant women who are HIV positive to receive appropriate treatment at birth
2. For the infant to be treated and followed up following birth and receive required testing to minimize the risk of mother to child transmission
3. To offer support and counseling to the family
4. To provide education and support to staff involved in the care of woman who are HIV positive in pregnancy
5. For staff to observe universal precautions to minimize risk of transmission
6. For all families to establish early rapport with the care team
7. Australian Paediatric Surveillance Unit notified when an infant is born to a HIV positive mother to monitor patterns of perinatal exposure and uptake of interventions
HIV Exposed infant Management - One Page Summary and Checklist

Rationale

Contacts

Confidentiality

Maternal HIV status & testing in pregnancy

Antiretroviral therapy during pregnancy

Management of Labour & Birth

Management of the Neonate

Postnatal Antiretroviral prophylaxis for the baby

Other preventative strategies-breast feeding

Care and Investigations for the infant

Immunisations

Follow up

References

GUIDELINE

This Guideline does not replace the need for the application of clinical judgment in respect to each individual patient.

Rationale: Top

The purpose of this guideline is to outline the management of a HIV exposed infant with the aim to reduce the vertical transmission of HIV from mother to child. The natural history of mother to child transmission in developed/industrialized countries shows transmission rates of 25%. With the combined strategies of antenatal, intrapartum and neonatal highly active antiretroviral therapy (HAART), minimizing infant exposure to maternal blood and secretions, low risk delivery methods and not breast feeding, this can be reduced to 1-2%.

For information that is regularly updated, access the USA HIV treatment information service, perinatal guidelines on the title page of guideline.

This protocol is based on the NSW Statewide Paediatric HIV Service Policy, based at Sydney Children’s Hospital.
Contacts

For discussions during the week regarding perinatal and postnatal management contact Dr Paul Craven, Neonatologist. For after-hours, contact the Neonatologist on call.

An antenatal plan is made with each woman and her family and this is recorded in her notes and appropriate details are written in a consultation letter.

Confidentiality

Confidentiality of all information regarding the mother and the infant should be maintained at all times. No correspondence regarding the diagnosis should be forwarded without the mother’s consent.

Maternal HIV status & testing in pregnancy

HIV may be transmitted during pregnancy, birth or during breast feeding. Undiagnosed HIV infection during pregnancy has serious implication for the health of both mother and her child. Screening for HIV in early pregnancy enables the implementation of strategies to reduce the risk of mother to child transmission and the rate of disease progression in the mother.

The National HIV testing policy (92011) recommends universal antenatal HIV testing. All women should be informed that HIV testing is routinely performed for women booked to birth with JHH Maternity Services as part of their antenatal booking investigations in the first trimester.

Factors that increase the risk of mother to child transmission are:

- Low maternal CD4 counts
- High maternal viral load
- Prolonged rupture of membranes >4 hours
- Some obstetric interventions
- Breast feeding
- Lack of highly active retroviral therapy (HAART)

Women who are newly diagnosed should be given psychological support as well as advice on contact tracing: partner testing and testing for other sexually transmitted infections. All women who are HIV positive should have ongoing specialist obstetric care during their pregnancy and have ongoing discussion regarding measures to reduce the risk of mother to child transmission.

1. Maternal viral load suppression
2. Planned mode of birth
3. Minimizing obstetric interventions
4. Post exposure prophylaxis to the infant
5. Advantages of avoidance of breast feeding

Antiretroviral therapy during pregnancy

Prophylactic antiretroviral regimes are now widely accepted and are used in Australia with success. Most mothers in HNELHD are cared for by a team of HIV specialists who prescribe HAART for mothers. In general, combination antiretroviral regimes are more
effective if given to mothers than monotherapy. Longer courses are better than shorter courses. HAART is best started early in pregnancy for mothers not already on combination therapy. Antenatal management should be led by a specialist obstetrician and always occur in combination with the local HIV specialist.

After birth the majority of babies are treated with oral zidovudine (previously known as AZT) for 4 weeks. If there is a detectable viral load close to or at delivery, other antiretroviral agents may be required and this should be discussed with the HIV team at Sydney Children’s Hospital, (Phone: 02 9382 1111).

Oral zidovudine liquid is kept in the imprest drug cupboard in the Neonatal Intensive Care Unit. Should oral zidovudine be contraindicated, i.e.an infant not tolerating oral medication, the IV zidovudine solution is stocked in the satellite pharmacy.

Management of Labour & Birth

The additional advantage of caesarean section in women already on HAART and with effective viral control i.e. viral load < 1000 copies/ml or even undetectable viral load is not yet determined.

General principles

- Discussion on mode of birth should occur in the antenatal period
- If there is effective viral suppression the benefit of caesarean section is not known. If a woman has an undetectable viral load (<50copies/ml) by 36 weeks of gestation, an uncomplicated vaginal birth should be considered
- Detectable viral loads, even if low should be discussed on a case by case basis

Intrapartum zidovudine

There is no consensus whether this is required in women who have been on effective HAART regimes and have good viral suppression

Undetectable viral load, the current recommendation is that Intrapartum zidovudine can be omitted i.e. HAART > 4 weeks and viral load undetectable (<50copies/ml)

If there is a detectable viral load, intravenous zidovudine should be given

Maternal Zidovudine Regime if required:

| Loading dose | 2 mg/kg (maternal body weight) IV for one hour, followed by maintenance dose. |
| Maintenance dose | 1 mg/kg/hr (maternal body weight) by continuous IV infusion until delivery of the baby and cord clamping. |

Note: If the maternal HAART regimen contains stavudine (no longer used routinely in Australia) , then intrapartum zidovudine is contraindicated due to potential drug interaction.

Management of the Neonate

At Birth

- Staff to wear PPE
- Avoid artificial rupture of membranes
- Avoid scalp electrodes and fetal blood sampling
- Gently wipe the baby’s eyes at birth to remove secretions.
- Towel dry baby.
- Resuscitation, if needed, should continue as per normal taking care to avoid damage to mucous membranes during suction.
- Routine skin to skin contact between mother and baby should still be encouraged.
- The baby should be bathed as soon as possible after the initial period of skin to skin contact to remove any maternal blood.
- All injections (Vitamin K and Hepatitis B vaccination) must be delayed until after the bath with the area thoroughly cleaned.
- Notify: NICU Registrar/NP of birth, to ensure review and commencement of postnatal medication.

**Postnatal Antiretroviral prophylaxis for the baby**

Postnatal prophylaxis should commence on all babies 6-12 hours following birth. In a low risk infant, i.e. a mother with a viral load < 50 copies/mL and mother to child transmission prevention criteria is in place, monotherapy with zidovudine alone is indicated for 4 weeks. If the baby vomits within 15 minutes of dose, repeat the dose. In a higher risk infant, please discuss with the care team at SCHN early, in case additional antiretroviral medications are required.

**Neonatal Zidovudine Regime (Refer to NICU drug Protocol)**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosages</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zidovudine Syrup</td>
<td>ORAL</td>
<td>IV (IF NEEDED) (200mg/20mL: 10 mg/ml)</td>
</tr>
<tr>
<td>Syrup concentration:</td>
<td>TERM</td>
<td>TERM</td>
</tr>
<tr>
<td>10 mg/ml</td>
<td>4mg/kg per dose, Give 12 hourly</td>
<td>3.0 mg/kg per dose</td>
</tr>
<tr>
<td></td>
<td>PREMATURE</td>
<td>Give  12 hourly</td>
</tr>
<tr>
<td></td>
<td>30 34 weeks (Discuss with SCH)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 2 mg/kg, 12 hourly for 2 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Then 2 mg/kg, 8 hourly for 2 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 30 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 2 mg/kg, 12 hourly (for 4 weeks)</td>
<td></td>
</tr>
<tr>
<td>Lamivudine (3TC)</td>
<td>Must be discussed with specialist before</td>
<td>Zidovudine should be given for total of 4</td>
</tr>
<tr>
<td>Oral solution</td>
<td>commencing therapy</td>
<td>weeks Cease IV once infant is established</td>
</tr>
<tr>
<td>concentration:</td>
<td></td>
<td>on oral feeding and commence oral therapy</td>
</tr>
<tr>
<td>10 mg/ml</td>
<td>2mg/kg BD</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 weeks</td>
</tr>
</tbody>
</table>
**Nevirapine (NVP) Oral suspension concentration:** 10 mg/ml

- Must be discussed with specialist before commencing therapy

**No maternal nevirapine in the peripartum period**
- 2 mg/kg/dose, once daily for first week
- 4 mg/kg/dose, once daily for second week
- Stop after week 2

*If mother has had > 3 days of nevirapine (antenatal):*
- 4 mg/kg/dose, once daily for 2 weeks

Nevirapine has a long half-life. This regimen allows for a 2 week “tail” cover with the other 2 ARVs (zidovudine + lamivudine)

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**Other postnatal preventative strategies - Feeding**

Breast feeding by mothers who are HIV positive, increases the risk of mother to child transmission. Although the benefits of breastfeeding are recognized, the mother should be advised of the additional risks of HIV, so she can make an informed decision. The only way to reduce risk completely is to avoid exposing the infant to breast milk.

**Care and Investigations for the infant:**

- During the pregnancy, the fetus passively acquires maternal HIV antibodies across the placenta and carries these for 12-18 months. The fetus is not infected but rather has acquired the antibodies from the mother and so will test HIV antibody positive when born.

- For the diagnosis of HIV infection in babies, the virus needs to be detected first and later quantified. This is done by demonstrating viral DNA by PCR.

- Any positive PCR test must be confirmed as soon as possible by repeat test to confirm infection. **HIV infection is diagnosed by two positive HIV virologic tests performed on separate blood samples, regardless of age.**

- A negative initial PCR in the neonatal period needs follow up with multiple negative tests to age 6 months to confirm uninfected status supported by no physical signs of infection. A final test (HIV antibody test) is done at 18 months to confirm that the baby has cleared passively acquired maternal antibodies. The sensitivity of a single HIV DNA PCR test performed at < 48 hours of age is less than 40 %, but increases to more than 90% by 2-4 weeks of age. If a PCR is positive, the test is always repeated as soon as possible (on a new sample) before confirmation of an infected baby is made.

- All infants of HIV positive mothers are followed up at a specific neonatal clinic

**Note:** Informed parental consent is required to test the baby.
Suggested testing regimen for infants at risk:

<table>
<thead>
<tr>
<th>Time</th>
<th>Clinical review</th>
<th>PCR (EDTA)</th>
<th>HIV Antibody (clotted serum or lithium heparin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Week 4</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>3 months</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>6 months</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>12 months</td>
<td>+</td>
<td>-</td>
<td>+ *</td>
</tr>
<tr>
<td>18 months</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>

*If all PCR’s are negative, then only clinical review needed at 12months

Other Antiretroviral (if indicated)

- **Lamivudine (3TC)** – 2 mg/kg/dose every 12 hours to start within 8 hours of birth. May be commenced if mother on combination therapy.
- **Nevirapine** – 2 mg/kg as a single dose ASAP within 3 days of delivery

Immunisations

- Routine immunisations should be given according to the national schedule. No live vaccinations should be given until it is confirmed that the infant is HIV negative.
- Inactive injectable poliomyelitis immunisation is given instead of oral immunisation to protect immunocompromised members of the family.
- MMR **should not** be given in infants with severe immunosuppression.
- Discuss with Sydney Children’s Hospital infectious disease team if concerned

Follow Up

- The family should continue to be well supported with regular review, counseling and should be linked into additional support services.
- Babies who are found to be infected should be followed up closely by a paediatric HIV team for treatment and prevention of other congenital infections associated with HIV infection.
- Notification to the APSU (Australian Paediatric Surveillance Unit) as a notifiable disease. See “Australian Paediatric Surveillance Unit-Study Protocol”
HIV exposed infant management JHCH_NICU_11.02

References


Guidelines for Paediatric Management of Infants born to HIV positive pregnant women, Auckland Hospital, New Zealand.

HIV Infection in Pregnancy and Neonatal Diagnosis. A guide to management. SCH, Randwick, Royal Hospital for Women & Albion Street Centre

HIV Management. Neonatal Clinical Guidelines, King Edward Memorial Hospital, Perth, Western Australia.

HIV Perinatal, Royal Children’s Hospital Melbourne.


RPA Newborn Care Guidelines, HIV Infection: Prevention of Perinatal transmissions. Royal Prince Alfred Hospital,

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FEEDBACK
Any feedback on this document should be sent to the Contact Officer listed on the front