Local Guideline

John Hunter Children's Hospital
CHILDREN, YOUNG PEOPLE AND FAMILIES

NSW GOVERNMENT Health
Hunter New England Local Health District

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

Hyperlink to Guideline

Keywords	baby, HIV, neonate, maternity, newborn, Zidovudine,JHCH,NICU
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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 http://www0.health.nsw.gov.au/policies/pd/2014/pdf/PD2014_036.pdf
- Australian Paediatric Surveillance Unit-Study Protocol http://www.apsu.org.au/assets/current-studies/HIV-Study-Hivprotocol-APSU-Final-030613.pdf
- NSW HIV Strategy 2016-2020 http://www0.health.nsw.gov.au/policies/ib/2015/pdf/IB2015_062.pdf

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.
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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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Note: Over time links in this document may cease working. Where this occurs please source the document in the PPG Directory at: http://ppg.hne.health.nsw.gov.au/

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

Acronym or Term	Definition
ARV	Anti- retro viral
AZT	Zidovudine
CD4	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
HAART	Highly Active antiretroviral therapy
HIV	Human Immunodeficiency Virus
HNELHD	Hunter New England Local Health District
PCR	Polymerase Chain Reaction - is used to amplify a specific region of a DNA strand
PPE	Personal protective equipment
Viral DNA	virus that has the molecule Deoxyribonucleic acid as its genetic material

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

(Ctrl+Click on **Coloured** words to jump to that section)

GUIDELINE

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

Rationale:

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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

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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

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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

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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

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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

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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

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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

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Post natal 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)

Drug Name	Dosages		Duration
Zidovudine Syrup concentration: 10 mg/ml	ORAL **TERM** • 4mg/kg per dose, Give 12 hourly **PREMATURE** **30 34weeks** (Discuss with SCH) • 2 mg/kg, 12 hourly for 2 weeks • Then 2 mg/kg, 8 hourly for 2 we**eks** **< 30 weeks** • 2 mg/kg, 12 hourly (for 4 weeks)	IV (IF NEEDED) **(200mg/20mL: 10 mg/ml)** **TERM** • 3.0 mg/kg per dose • Give 12 hourly **PREMATURE** **30 – 34 weeks** (Discuss with SCH) • 1.5 mg/kg per dose • Give 12 hourly	**Zidovudine should be given for total of 4 weeks Cease IV once infant is established on oral feeding and commence oral therapy**
Lamivudine (3TC) Oral solution concentration: 10 mg/ml	• Must be discussed with specialist before commencing therapy • 2mg/kg BD		**4 weeks**

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)**	**2 weeks**

Other postnatal preventative strategies- Feeding

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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.

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Care and Investigations for the infant:

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- 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:

Time	Clinical review	PCR (EDTA)	HIV Antibody (clotted serum or lithium heparin)
Week 1	+	+	-
Week 4	+	+	-
3 months	+	+	-
6 months	+	+	-
12 months	+	-	+ *
18 months	+	-	+

*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

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- 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

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- 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"

References

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FEEDBACK

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