

HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PREGNANCY: PREVENTION OF MOTHER-TO-CHILD-TRANSMISSION (MTCH) - SCH

PRACTICE GUIDELINE[®]

DOCUMENT SUMMARY/KEY POINTS

Women with HIV infection will receive a multi-disciplinary, patient-centred and individualised approach to treatment and care that supports the best possible outcome for both the mother and baby.

- Women living with HIV who are pregnant require an integrated multidisciplinary approach to care. This includes obstetricians, midwives, specialist nurses, and paediatric and adult HIV physicians.
- Confidentiality of information regarding the woman and her infant once born should be maintained at all times. Caregivers must not assume others are aware of the woman's HIV status or that the woman is prepared for others to know her HIV diagnosis. The woman's consent should be sought prior to forwarding correspondence regarding the diagnosis to others.
- This document contains information about :
 - Key preventative strategies to reduce the risk of HIV mother to child transmission
 - Care and management of the infant
 - Contacts and Further Information
- More information about the NSW Paediatric HIV Service based at Sydney Children's Hospital Network, Randwick and consumer-friendly resources are available at: <http://www.schn.health.nsw.gov.au/parents-and-carers/our-services/immune-deficiency-and-hiv/sch>

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1 st December 2019	Review Period: 3 years
Team Leader:	Paediatric Infectious Diseases Physician	Area/Dept: Immunology/ID/HIV

- For regularly updated information, access the U.S. Department of health and Human Services, perinatal guidelines at <https://aidsinfo.nih.gov/guidelines/html/3/perinatal/143/introduction> or the British HIV Association (BHIVA) pregnancy guidelines at www.bhiva.org/pregnancy-guidelines.aspx
- Reference algorithms: link to the Australasian Society for Infectious Diseases (ASID) *Management of Perinatal Infections* guidelines – see “HIV”. These algorithms represent a summary of the current recommendations <https://www.asid.net.au/resources/clinical-guidelines>

CHANGE SUMMARY

Some key changes have been made following the release of the British HIV Association (BHIVA) guidelines for the management of HIV infection in pregnant women 2018 (2019 interim update).¹ In summary, these changes are:

1. Infant HIV post-exposure prophylaxis (PEP) should be commenced within 4 hours of birth.
2. HIV mother-to-child transmission (MTCT) risk stratification of pregnancies falls into 3 categories (see Table 1 for criteria):
 - a. Very low risk: infants recommended to receive 2 weeks of zidovudine (AZT) monotherapy.
 - b. Low risk: infants recommended to receive 4 weeks AZT monotherapy.
 - c. High risk: infants recommended to receive combination HIV PEP, please consult the paediatric HIV service prior to commencing.

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READ ACKNOWLEDGEMENT

- The following staff should be aware of this policy. Healthcare workers who may be caring for pregnant women with HIV infection or infants born to women with HIV infection, and this may include: obstetricians, midwives, nurses, paediatricians, paediatric or adult HIV physicians

This policy was edited and modified by the NSW Paediatric HIV Service based at Sydney Children's Hospital Network, Randwick in conjunction with services providing care to HIV positive women across the SESLHD. It has been developed in conjunction with the Royal Hospital for Women (RHW), Randwick, Prince of Wales Hospital (POWH), Randwick, and The Albion Centre (TAC), Surry Hills.

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SUMMARY

Women living with HIV who are pregnant require an integrated multidisciplinary approach to care. This includes obstetricians, midwives, specialist nurses, and paediatric and adult HIV physicians.

Confidentiality and privacy

Confidentiality of information regarding the woman and her infant once born should be maintained at all times. Caregivers must not assume others are aware of the woman's HIV status or that the woman is prepared for others to know her HIV diagnosis. The woman's consent should be sought prior to forwarding correspondence regarding the diagnosis to others.

Key preventative strategies

HIV MTCT can occur during pregnancy or labour, or via breastfeeding. Preventative strategies are designed to minimise the risk of transmission. In Australia, the risk of HIV MTCT is <1% when the following preventative strategies are in place.

1. Maternal viral load suppression throughout pregnancy
 - i. Antenatal HIV testing is recommended for all pregnant women – this may need to be repeated if there is ongoing HIV exposure throughout pregnancy
 - ii. Antiretroviral therapy (ART) should be commenced before pregnancy if possible, or as soon as possible
 - iii. HIV viral load testing during pregnancy and prior to delivery is necessary to ensure viral suppression is achieved and maintained, and to guide interventions at time of delivery.
2. Mode of delivery and minimising obstetric/perinatal interventions
 - i. Recommendations for mode of delivery and intrapartum AZT are dependent on HIV viral load
3. Newborn PEP
 - i. Postnatal ART should be commenced within 4 hours of birth.
 - ii. For very low risk* HIV MTCT: AZT monotherapy for 2 weeks is recommended.
 - iii. For low risk HIV* MTCT: AZT monotherapy for 4 weeks is recommended.
 - iv. For high risk* HIV MTCT: combination ART** is generally recommended, to be discussed with the paediatric HIV service prior to commencing.
 - **Table 1 provides criteria for HIV MTCT risk stratification and recommendations for infant HIV PEP.*

- ***Table 2 provides dosing information for infant ART. Dosing information for agents other than AZT are provided, but these must be discussed individually with the paediatric HIV service.*

4. Mode of feeding

- i. Formula feeding is recommended, with avoidance of breastfeeding. In circumstances where the mother wishes to breast feed, please discuss with the paediatric HIV service to develop a plan for safer breast feeding involving a harm minimisation strategy.

Care and management of the infant

All infants who have been perinatally exposed to HIV should be regularly reviewed, in coordination with a 'Care Plan' from the paediatric HIV team.

Components of infant management

1. HIV PEP (usually AZT monotherapy for 2-4 weeks)
2. Diagnostic testing up to 18 months of age
3. Immunisations (according to the National Immunisation Program Schedule)
4. Support and linkage with primary care

Contacts and Further Information

- E: www.schn.health.nsw.gov.au/parents-and-carers/our-services/immune-deficiency-and-hiv/sch
- T: 02 9382 1654 (Sydney Children's Hospital HIV Service Clinical Nurse Consultant) or 02 9382 1111 (Sydney Children's Hospital switchboard - ask to speak to Paediatric or Adult Infectious Diseases physician on-call for urgent advice)

1 NSW PAEDIATRIC HIV SERVICE

1.1 BACKGROUND INFORMATION

The NSW Paediatric HIV Service based at Sydney Children's Hospital, Randwick provides care, counselling and support to pregnant women living with HIV and their families, and to assist with the prevention of HIV MTCT. The Service also provides a consultative service for clinicians caring for pregnant women who are infected with HIV across NSW and nationally, and to physicians involved in the care of children living with HIV and their families. Please see the list below for contacts for the Paediatric HIV Service.

1.2 SERVICE DETAILS

Available at:

<http://www.schn.health.nsw.gov.au/parents-and-carers/our-services/immune-deficiency-and-hiv/sch>

1.3 CONTACTS

Business hours: The best contacts during the week are:

Clinical Nurse Consultant (CNC) Phone: (02) 9382 1654 (direct line)
or Switchboard (02) 9382 1111, pager 44445
Mobile: 0413 085 469

Senior Social Worker Phone: (02) 9382 1851 (direct line)
or Switchboard (02) 9382 1111, pager 47065

After hours or on weekends:

Infectious Diseases Service on-call Phone: (02) 9382 1111.
(ID Consultant or ID Fellow) Ask to be put through to the ID staff on call
for children.

2 CARING FOR POSITIVE WOMEN DURING PREGNANCY

HIV in pregnancy requires an integrated multidisciplinary approach to care for women and babies. This includes obstetricians, midwives, specialist nurses, paediatric and adult HIV specialists, and may include additional health professionals.

The Paediatric HIV Team at Sydney Children's Hospital is a multi-disciplinary team, including medical doctors, a clinical nurse consultant, a social worker and a dietician. It is recommended that the Paediatric HIV team be consulted as early as possible in pregnancy in order to be involved in perinatal counselling for the woman. The objectives of early involvement by the paediatric HIV team are:

- To establish a relationship with the pregnant woman (and her partner if relevant)
- To provide a written care plan and advise on optimal strategies to minimise the risk of HIV MTCT for the individual woman and baby
- To prepare the woman for what to expect in terms of medications and testing when the baby is born
- To provide education and support to other healthcare staff involved in the care of the woman
- To provide psychosocial support around the wellbeing of the woman and her baby

The Care Plan provides a summary of relevant information and the steps required for HIV MTCT prevention, suitable for use by healthcare workers caring for the woman and baby. The Care Plan is normally sent to the referring HIV physician, the obstetrician, delivery suite and a copy sent to the pregnant woman, plus others if relevant e.g. the general practitioner. This is done in consultation with the pregnant woman, in recognition of privacy.

CONFIDENTIALITY & PRIVACY

Health care providers **must not** assume that partners, parents, relatives, friends or even other health care workers are aware of the woman's HIV status. Neither can they assume that the woman is prepared for any of these contacts to know. Health care professionals need to respect privacy and confidentiality in this regard. Ideally disclosure should only be done with the woman's prior consent, when required, except where necessary for clinical care, in accordance with NSW laws and NSW Health policies.

2.1 HIV TESTING IN PREGNANCY

HIV may be transmitted from mother to infant during pregnancy, labour, or via breastfeeding. The most important information to enable the implementation of MTCT prevention strategies is to know the woman's HIV diagnosis prior to, or early in the pregnancy. Effective MTCT prevention strategies significantly minimise the risk of HIV MTCT. In well-resourced countries, the risk of HIV MTCT is now <1% when effective MTCT prevention strategies are in place.^{2, 3, 4}

- The National HIV testing Policy (2017) states that antenatal HIV testing should be recommended to all women at their first antenatal visit.⁵ It should not be assumed that any pregnant woman has been tested for HIV without specific information confirming the testing and result.
- The woman should be informed about the tests being performed as part of the antenatal screen, including HIV testing and provide consent. ⁵
- All women contemplating pregnancy or seeking antenatal care should be made aware of the benefits of diagnosis of HIV Infection and management, and prevention strategies available for both the mother and the infant.
- Women with limited literacy, or from culturally and linguistically diverse backgrounds, require appropriate educational resources. Material using other media (video, audio, multimedia) and in languages other than English may be necessary.
- Women from culturally and linguistically diverse backgrounds should be offered access to accredited interpreting services.
- Women who present in labour or an advanced stage of pregnancy who have not had an HIV test at an earlier stage should be offered urgent HIV testing.

2.2 HIV MTCT RISK FACTORS

Factors associated with a higher risk of MTCT of HIV include: ⁶⁻⁸

- High maternal viral load
- Low maternal CD4 count
- Lack of effective antiretroviral therapy for prevention of MTCT⁷
- Prolonged rupture of membranes >4 hours (in the absence of viral suppression)⁹
- Obstetric interventions such as fetal blood sampling or fetal scalp clips
- Mode of delivery (vaginal versus caesarean section) ^{8,10}
- Breast feeding¹¹
- Mixed feeding (breast milk feeding and solids)¹²

A high maternal viral load or low CD4 count (both of which indicate either high HIV viral activity or advanced HIV infection/immune dysfunction) are most significantly associated with transmission of HIV.

2.3 MATERNAL STRATEGIES TO REDUCE HIV MTCT

Extensive and significant advances in the area of HIV MTCT prevention have been made. Effective combination ART to achieve undetectable viral loads in pregnant women, combined with strategies that include planned (elective) caesarean section (if viral suppression is not optimal), avoidance of invasive obstetric procedures, infant postnatal prophylaxis, and formula feeding of infants (where feasible) has reduced the risk of HIV MTCT to <1%.^{2,13}

i. Maternal viral suppression

- Maintenance of an 'undetectable HIV viral load' (<50 copies/ml) with combination ART at or after 36 weeks gestation.

ii. Delivery mode

- Recommend vaginal delivery if maternal viral load is undetectable
- Consider caesarean section if viral load 50–399 copies/ml
- Recommend planned caesarean section if viral load >400 copies/ml

In the case of planned vaginal delivery (undetectable HIV viral load): the mother should be advised to present to delivery suite as soon as possible if there is ruptured membranes or as soon as labour / contractions begin.

iii. Intrapartum AZT

- None if viral load is undetectable
- Consider if viral load 50–1000 copies/mL
- Recommended if viral load >1000 copies/mL
 - If intrapartum AZT is needed in the case of vaginal delivery: intra-partum AZT should be commenced at the start of labour or rupture of membranes (whichever is earlier) and continued for the duration of labour and ceased after delivery. Maternal ART will remain unchanged and managed by her own HIV team.
 - If intrapartum AZT is needed in the case of elective caesarean delivery: intra-partum AZT should be commenced 3 hours prior to caesarean section and ceased after delivery. Maternal ART will remain unchanged and managed by her own HIV care team.
 - Dose of intrapartum IV AZT: 2 mg/kg/hr for the first hour, then 1 mg/kg/hr until delivery

iv. Feeding mode

- Formula feeding is recommended, with avoidance of breastfeeding†

†For women who wish to breastfeed extra monitoring is required: ways to achieve this and reduce risk of transmission can be discussed with the paediatric HIV service, and further information can be found in BHIVA pregnancy guidelines at www.bhiva.org/pregnancy-guidelines.aspx

3 CARE AND MANAGEMENT OF THE INFANT

3.1 INFANT POST-EXPOSURE PROPHYLAXIS

Postnatal ART should be commenced within 4 hours of birth.

- v. For very low risk* HIV MTCT: AZT monotherapy for 2 weeks is recommended.
- vi. For low risk HIV* MTCT: AZT monotherapy for 4 weeks is recommended.
- vii. For high risk* HIV MTCT: combination ART** is generally recommended, to be discussed with the Paediatric HIV Service prior to commencing.

**Table 1 provides criteria for HIV MTCT risk stratification and recommendations for infant HIV PEP.*

***Table 2 provides dosing information for infant ART. Dosing information for agents other than AZT are provided, but these must be discussed individually with the Paediatric HIV Service.*

3.2 HIV TESTING IN INFANTS

Whilst the diagnosis of HIV infection in adults is readily established by the detection of HIV antibodies, the situation is more complex in babies born to HIV positive women. Maternal HIV antibodies cross the placenta, therefore these babies will be “HIV antibody positive” as the test will detect maternal HIV antibodies. The HIV antibody test alone cannot be used to make a positive diagnosis in infants, as it can take up to 18 months for a baby to clear maternal HIV antibodies. For this reason, polymerase chain reaction (PCR) testing is used to confirm presence of HIV in infants. Either HIV proviral DNA or RNA PCRs are acceptable tests. Multiple negative PCRs are required to confirm an “HIV uninfected” status in exposed infants. Testing should occur **at least 2 weeks and 2 months after PEP has ceased**. If a PCR is positive, the test is **always repeated** as soon as possible (on a new sample).

A confirmatory HIV antibody test at 18 months to document “seroreversion” (clearance of maternal HIV antibodies) is recommended. This further confirms the infant’s HIV status.

Two useful resources for further information on perinatal testing and infant management are:

- The U.S. Department of Health and Human Services Perinatal Guidelines¹³, available at <https://aidsinfo.nih.gov/guidelines/html/3/perinatal/0> [regularly updated] and
- BHIVA guidelines for the management of HIV infection in pregnant women¹⁴, available at <https://www.bhiva.org/pregnancy-guidelines> [updated 2018, interim addition 2019]

Table 3 summarises the testing and clinical follow-up schedule for perinatally HIV-exposed children.

- HIV nucleic acid testing
 - Either HIV proviral DNA PCR or RNA HIV PCR can be used for very low and low risk cases.¹⁵
 - Both tests are highly specific and of equivalent sensitivity (60% at birth, 90% at 1 month and 100% at 3 and 6 months, with high concordance).¹⁶
 - RNA PCRs are in general more widely available, and may provide superior amplification of non-B HIV subtypes.
 - Testing should occur at **least 2 weeks and 2 months** after postnatal PEP is stopped.
 - Usual schedule: Week 1, then 4-6 weeks and 3 months of age.
 - Note: where HIV MTCT risk is deemed to be >2%, **testing as soon as possible after birth and within 48 hours of age is recommended**
- Presumptive exclusion of HIV infection
 - In very low or low risk HIV MTCT settings, exclusion of HIV can be presumed based on 2 negative virologic tests (RNA or DNA PCR), obtained at least 2 weeks and 2 months after PEP has stopped (i.e. in most infants at 4-6 weeks and 3 months of age).
- HIV antibody
 - Test at 18 months. Almost all infants clear maternal HIV antibodies by 18 months of age. Documenting clearance of HIV antibody is recommended for further confirmation of the absence of HIV infection in the infant. This is the same test used to diagnose or exclude HIV infection in older children and adults.
 - If seroreversion has not occurred, review results in context of the child's clinical history. In most cases, this represents low-level persisting maternal antibody – re-test at 24 months of age and provide counselling and support to family.

3.3 **PNEUMOCYSTIS JIROVECI PNEUMONIA (PJP) PROPHYLAXIS**

(previously known as *Pneumocystis carinii* pneumonia (PCP))

- PJP prophylaxis is not indicated if the risk of HIV MTCT is very low or low (<1 %).
- If PJP prophylaxis is indicated, it should start after postnatal PEP is completed – usually at 4-6 weeks of age.
- Sulfamethoxazole-trimethoprim is used.
 - PJP prophylaxis is discontinued once it is deemed that the baby is not infected (via diagnostic testing).
- Dosing regimen:
 - Dose of sulfamethoxazole-trimethoprim for prophylaxis in babies <6 month of age is **100 mg sulfamethoxazole - 20 mg trimethoprim once daily**

3.4 **INFANT IMMUNISATIONS**

Routine childhood immunisations should be given to all infants according to the National Immunisation Program Schedule. This can be done either through follow-up visits at this hospital or through the family's local general practitioner.

3.5 **SUPPORTS**

The family should be well linked to supports that are available to them. Discharge planning is paramount and should include contact if appropriate to services available to all women such as general practitioners, Child and Family Health Centres, and community supports.

The Paediatric HIV Service provides clinical and psychosocial support to the family including:

- Counselling support
- Referrals to other HIV support services (i.e. Pozhet, Multicultural HIV and Hepatitis Service, HIV Outreach Teams, Bobby Goldsmith Foundation, HALC)
- Referrals to family support services
- “Camp Goodtime” (national camp for children and families with a member living with HIV)

GLOSSARY

ART	Antiretroviral therapy
AZT	Zidovudine
BHIVA	British HIV Association
HIV	Human Immunodeficiency Virus
NVP	Nevirapine
MTCT	Mother-to-child transmission
PCR	Polymerase Chain Reaction
3TC	Lamivudine

TABLE 1. HIV MOTHER-TO-CHILD TRANSMISSION RISK STRATIFICATION

(Adapted from the BHIVA guidelines on the management of HIV in pregnancy and postpartum 2018, 2019 interim update)¹

Risk stratification	Criteria	Infant post-exposure prophylaxis
Very low risk	<ul style="list-style-type: none"> • Maternal combination ART for more than 10 weeks. • Two documented maternal HIV viral loads <50 copies/mL during pregnancy and at least 4 weeks apart • Maternal HIV viral load <50 copies/mL at or after 36 weeks gestation 	2 weeks zidovudine monotherapy.
Low risk	<ul style="list-style-type: none"> • Maternal HIV viral load is <50 copies/mL at or after 36 weeks, but other 'very low risk' criteria are not met. • Infant born <34 weeks gestation and most recent maternal HIV viral load is <50 copies/mL. 	4 weeks zidovudine monotherapy.
High risk	<ul style="list-style-type: none"> • Maternal HIV viral load at delivery is known or likely to be >50 copies/mL. • Uncertainty about recent maternal adherence to combination ART. • Maternal HIV viral load is not known. 	Discuss with Paediatric HIV service for advice.

TABLE 2. INFANT ANTIRETROVIRAL DOSING RECOMMENDATIONS (POSTNATAL PROPHYLAXIS)^{13,14}

Drug Name	Dosages		Duration
Zidovudine (AZT) Syrup concentration: 10 mg/ml	ORAL <u>TERM INFANT</u> <ul style="list-style-type: none"> 4mg/kg/dose, 12-hourly <u>PRETERM INFANT</u> 30 – 34 weeks <ul style="list-style-type: none"> 2 mg/kg/dose, 12-hourly for 2 weeks Then 2 mg/kg/dose, 8-hourly for 2 weeks < 30 weeks <ul style="list-style-type: none"> 2 mg/kg/dose, 12 hourly 	IV (concentration: 10 mg/ml) <u>TERM INFANT</u> <ul style="list-style-type: none"> 3.0 mg/kg/dose, 12-hourly^a <u>PRETERM INFANT</u> <ul style="list-style-type: none"> 1.5 mg/kg/dose, 12-hourly 	Should be given for total of 2-4 weeks Cease IV once infant is established on oral feeding and commence oral formulation
Lamivudine (3TC) Oral solution concentration: 10 mg/ml	<ul style="list-style-type: none"> 2mg/kg/dose, 12-hourly 		4 weeks

Drug Name	<u>Dosages</u>	Duration
Nevirapine (NVP) Oral suspension concentration: 10 mg/ml	<p><u>No maternal NVP in the peripartum period</u></p> <ul style="list-style-type: none"> • 2 mg/kg/dose, once daily for <u>first week</u> • 4 mg/kg/dose, once daily for <u>second week</u> • Stop after week 2 (NB: “tail” of AZT + 3TC needs to continue after for 2 weeks) <p><u>If mother has had >3 days of antenatal NVP</u></p> <ul style="list-style-type: none"> • 4 mg/kg/dose, once daily for <u>2 weeks</u> (NB: “tail” of AZT +3TC needs to continue after for 2 weeks) <p>NVP has a long half-life. This regimen allows for a 2 week “tail” cover with the other 2 ARVs (AZT + 3TC)</p>	2 weeks

NOTE: The dosing for AZT differs in the BHIVA and USA guidelines. We have used the BHIVA recommendations with the exception of a (IV dosing) which is from the USA Perinatal Guidelines.

NOTE: Lopinavir/ritonavir (Kaletra) is contraindicated in term newborns <14 days old or in premature babies until ≥14 days past their due date (due to reports of adrenal dysfunction).

TABLE 3. TESTING AND CLINICAL FOLLOW UP OF THE INFANT

Note: testing schedules where MTCT risk very low or low (<1%) (ie: mother had “undetectable” viral load at or after 36 weeks gestation and MTCT prevention strategies in place)

Time	TEST*	CLINICAL CARE
Week 1 (anytime in the week while in hospital)	HIV RNA PCR or HIV DNA PCR	<ul style="list-style-type: none"> Clinical review AZT syrup (4 mg/kg/dose, 12-hourly) for 2 weeks ('Very low risk' babies) or 4 weeks ('Low risk' babies) (start within 4 hours of birth)
Week 6	HIV RNA PCR or HIV DNA PCR	<ul style="list-style-type: none"> Clinical review Ensure AZT syrup was stopped at WEEK 2 ('Very low risk' babies) or WEEK 4 ('Low risk' babies) Infant vaccines as per National Immunisation Program
3 months	HIV RNA PCR or HIV DNA PCR	<ul style="list-style-type: none"> Clinical review Infant vaccines as per National Immunisation Schedule
6 months	No test Clinical review	<ul style="list-style-type: none"> Clinical review Infant vaccines as per National Immunisation Schedule
12 months	No test Clinical review	<ul style="list-style-type: none"> Clinical review Infant vaccines as per National Immunisation Schedule
18 months	HIV antibody	<ul style="list-style-type: none"> Clinical review Infant vaccine as per National Immunisation Schedule

*Note: It is recommended that testing occur at least 2 weeks and 2 months after postnatal ART prophylaxis is stopped.

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