HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PREGNANCY, BIRTH AND POSTPARTUM PERIOD

This LOP is developed to guide clinical practice at the Royal Hospital for Women. Individual patient circumstances may mean that practice diverges from this LOP.

1. AIM

- Prevention of mother to child transmission (MTCT) of Human Immunodeficiency Virus (HIV) infection and maintenance of maternal health

2. PATIENT

- Pregnant woman with HIV

3. STAFF

- Midwifery, nursing and medical staff
- Student midwives

4. EQUIPMENT

- Venepuncture equipment + blood tubes
- Personal protective equipment (PPE)

5. CLINICAL PRACTICE

Antenatal management and the use of anti-retroviral therapy in pregnancy

- Refer HIV positive woman to Maternal Fetal Medicine department for antenatal care and planning
- Arrange tests/visits as per antenatal care schedule (as per appendix 1) in addition to usual antenatal screening
- Discuss options for non-invasive prenatal screening, which is preferred to invasive procedures such as amniocentesis or Chorionic Villus Sampling (CVS)
- Defer any invasive prenatal diagnostic testing until HIV status of the woman is known and ideally until Viral Load (VL) has been adequately suppressed
    - Where invasive diagnostic testing cannot be delayed and the woman is not on treatment, consultation with Infectious Disease (ID) should be arranged to discuss treatment. This includes the initiation of integrase strand transfer inhibitor containing antiretroviral therapy (ART), and consideration of the addition of s a single dose of Nevirapine two to four hours prior to the procedure
- Discuss recommendation for ART during pregnancy
    - Commence ART at the start of the second trimester (unless the HIV VL is >100,000 RNA copies/mL or the CD4 T-cell count is less than 200/mm^3, when ART should be commenced sooner – consult adult ID) and all should have commenced therapy before week 24 of gestation diagnosis (see appendix 2). This treatment will be prescribed by the woman's HIV physician
    - Perform and review HIV resistance testing prior to initiation of treatment except for late presentation (≥ 28weeks gestation, where treatment should be commenced without delay)

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HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PREGNANCY, BIRTH AND POSTPARTUM PERIOD cont'd

- Prevent mother to child transmission (MTCT) by aiming to have a maternal VL undetectable by the third trimester. Consult with woman's HIV physician around testing of VL:
    - Usually they will arrange testing 2–4 weeks after commencing or changing ART, then monthly until undetectable
    - At least once every trimester, and
    - At 34-36 weeks
- Arrange liver function tests (LFTs) on initiation of treatment and at routine antenatal bloods
    - If co-infection with Hepatitis B (HBV) and/or Hepatitis C (HCV), LFTs may be repeated at two and four weeks after commencing treatment to detect hepatotoxicity or immune reconstitution inflammatory syndrome
- Review □mmunization status recommending Influenza (in season), Hepatitis B, Diphtheria Tetanus Pertussis (dTpa) and pneumococcus
- Discuss mode of birth depending on obstetric history, ART and VL in late pregnancy:
    - Recommend vaginal delivery (spontaneous or induced for usual obstetric indications) for woman on ART with a HIV VL at <50 HIV Ribonucleic acid (RNA) copies/mL plasma at 36 weeks
        - vaginal birth after caesarean section (VBAC) can be offered to woman with HIV VL <50 RNA copies/mL with no other obstetric contraindications
        - Plan caesarean section for obstetric indications, when plasma VL <50 RNA copies/mL, between 39-40 weeks
    - Consider planned caesarean section at 38-39 weeks for woman with a plasma VL of 50-399 HIV RNA copies/mL at 36 weeks, taking into account the actual VL, the trajectory of the VL, length of time on treatment, adherence issues, obstetric factors and the woman's wishes
    - Recommend caesarean section at 38-39 weeks when the VL is >400 HIV RNA copies/ml at 36 weeks, or if the mother is not on ART
- Consider Zidovudine (AZT) intravenously (IV) for birth if VL >1000 (see appendix 2). Obtain consent for this at 30 weeks, using Special Access Scheme Category A form and RHW consent for exceptional use medication form (see appendix 3). Pharmacy will arrange for medication to be available from 34 weeks on birth unit (This medication is also available in the after-hours drug cupboard)
- Recommend, for women with hepatitis B coinfection (HBV) in the absence of obstetric complications, normal vaginal delivery if the woman has fully suppressed HIV viral load on ART, irrespective of HBV viral load.
- Recommend, for women with hepatitis C coinfection (HCV) in the absence of obstetric complications, normal vaginal delivery if the woman has fully suppressed HIV viral load on ART
- Refer HIV positive woman to paediatric HIV team at Sydney Children's Hospital (SCH) for antenatal counselling on MTCT risks, prevention strategies and postnatal follow-up. This includes HIV investigations, immunisations and clinical follow up. Contact Clinical Nurse Consultant (CNC) Immunology & Infectious disease at SCH to arrange referral and visit on 93821654 or page: 44445
- Recommend against breast feeding (however if woman has an undetectable VL < 50 RNA copies/ml, and is very motivated, a collaborative plan for safe breastfeeding can be made. (See appendix 5)

HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PREGNANCY, BIRTH AND POSTPARTUM PERIOD cont'd

- Ensure woman's confidentiality antenatally, intrapartum and postpartum, as family members may be unaware of the woman's HIV diagnosis
- Consider drug interactions prior to prescribing any medication in woman who is taking ART
- Recommend the following if woman who has initiated ART in pregnancy has not suppressed VL to <50 HIV RNA copies/mL:
  - review adherence and concomitant medication
  - perform resistance testing (if appropriate)
  - consider therapeutic drug monitoring (TDM)
  - □ptimize to best regimen
  - consider intensification

Pre-labour rupture of membranes (term)

- Expedite delivery in all cases of term pre-labour spontaneous rupture of membranes aiming for birth within 24 hours:-
  - If maternal HIV VL is <50 HIV RNA copies/mL recommend immediate induction of labour with a low threshold for treatment of intrapartum pyrexia
  - Consider immediate caesarean section for woman with a last measured VL of 50–399 HIV RNA copies/mL, taking into account the actual VL, the trajectory of the VL, length of time on treatment, adherence issues, obstetric factors and the woman's wishes
  - Recommend immediate Caesarean section if maternal HIV VL is ≥400 RNA copies/mL plasma

Premature pre-labour rupture of membranes (PPROM)

- Expedite delivery when PPROM occurs between 34 to 37 weeks gestation, as per above term rupture of membranes
- Recommend IV antibiotics as per preterm labour guidelines to cover group B streptococcus
- Administer steroids when PPROM occurs at <34 weeks gestation. Virological control should be □ptimized and there should be multidisciplinary discussion about the timing and mode of delivery

Intrapartum

- Prescribe IV AZT as per appendix 4, for vaginal birth or caesarean section if indicated (see appendix 2)
- Give routine oral medications at usual times on day of birth
- Avoid artificial rupture of the membranes unless necessary. If indicated, care should be taken to avoid skin injury to the neonate. Amniotomy and oxytocin augmentation may be considered for usual indications
- Implement universal precautions for care of all women
- Do not perform invasive procedures e.g. fetal scalp electrodes or fetal blood sampling
- Perform episiotomy and instrumental delivery for standard obstetric indications only. Choice of instrument should be on standard obstetric indications. Avoid instrumental birth where possible if viral load ≥50 HIV RNA copies/mL
- Consider using blunt needles at caesarean section or during perineal repair. Consider using skin staples rather than subcuticular sutures at time of caesarean section to reduce needle stick injuries

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HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PREGNANCY, BIRTH AND POSTPARTUM PERIOD cont'd

- **Arrange urgent adult ID consultation for <u>untreated woman presenting in labour</u>[3]** (regarding treatment):-
    - Usual recommendation, woman should be given:
        - Stat dose of Nevirapine 200mg tablet orally, and
        - Commence on fixed-dose AZT with Lamivudine (Combivir 1 tablet twice per day (bd) orally), and
        - Raltegravir (400mg twice a day) orally,
        - As well as AZT IV, as per appendix 2[3] (these medications are available in the afterhours drug cupboard)
    - Untreated woman in <u>preterm labour</u>:
        - if the infant is unlikely to be able to absorb oral medications, consider the addition of double dose Tenofovir DF to further load the baby
- Arrange urgent adult and paediatric ID physician consultations

<u>Infant</u>

- Gently wipe the neonate's eyes free of secretions on delivery of the head
- Avoid suction use, only use if absolutely necessary, and be gentle to avoid mucous membrane damage
- Clamp the cord as soon as possible, milking between the clamps in the direction away from the neonate. Place a sponge over the cord before cutting to prevent blood spurt
- Towel dry the neonate. Clean the neonate as soon as possible to remove all signs of visible blood (bath neonate if appropriate)
- Ensure skin is thoroughly cleaned (with alcohol swab) prior to any procedures that will disrupt skin integrity e.g. Intramuscular Injection (IMI) Vitamin K
- Administer antiretroviral therapy as per Sydney Children's Hospital infectious diseases team recommendations. This should start within four hours of birth (see appendix 2)
- Arrange follow up as per the Sydney Children's Hospital management plan

<u>Postnatal Woman</u>

- Recommend woman to continue ART following birth.
- Avoid ergometrine to treat Postpartum Haemorrhage (PPH) in woman who is receiving protease inhibitors as a component of ART. Use only if alternative treatments such as prostaglandin F2 alpha, misoprostol, or oxytocin are unavailable (the need for pharmacologic treatment outweighs the risks). Ergometrine should be used in as low a dosage and for as short a period as possible
- Advise against breastfeeding. Medical officer to discuss and prescribe Dostinex ® prior to woman leaving birthing unit if appropriate
    - However a woman who is virologically suppressed on treatment with good adherence who chooses to breastfeed should be supported. They should be informed of the low risk of MTCT through exclusive breastfeeding and close monthly VL monitoring. They should be given written information on "The Safer Triangle" (see educational notes and appendix 5)
- Arrange □mmunization prior to discharge for dTpa (if not given in pregnancy), and influenza vaccine (if required). Discuss with ID team prior to prescribing Measles Mumps Rubella (MMR) vaccine, if rubella or measles non-immune

HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PREGNANCY, BIRTH AND POSTPARTUM PERIOD cont'd

- Discuss and prescribe contraception, including barrier methods, prior to discharge
- Discuss prevention of sexual transmission of HIV prior to discharge (see education notes)
- Discuss cervical screening prior to discharge and recommend screening within next two months if not up to date
- Arrange postnatal follow up for woman with ID team

6. DOCUMENTATION

- Medical record
- Personal Health Record
- Neonatal Care Plan
- Special Access Scheme (SAS) Category A form. The Therapeutic Goods Administration (TGA) form can be downloaded direct from the website. http://www.tga.gov.au/pdf/forms/access-forms-sas-categorya.pdf
- Exceptional use medication form

7. EDUCATIONAL NOTES

- Recommend all pregnant women have HIV screening at booking
- Ideally women with HIV should have pre-pregnancy counselling, reviewing treatment regimen, serology (hepatitis, syphilis, rubella, varicella zoster), pre-pregnancy folate, vaccinations, alcohol and smoking, diet and information about infections such as Sexually Transmitted Infections, Cytomegalovirus (CMV), as well as conception strategies. Preconception counselling can be arranged via Mothersafe or the complex pre-conception clinic if required
- A multidisciplinary approach should be taken to management of the pregnant woman with HIV. The team should consist of ID, obstetrics, midwifery, paediatrics, pharmacy, allied health, general practitioner and other specialists as required to give a holistic approach
- All women who are HIV positive and pregnant should receive ART treatment (which is a combination of at least three medications), to reduce the risk of perinatal transmission
- ART should generally be commenced in the second trimester, or earlier if there is an elevated viral load >100,000 HIV RNA copies/mL and/or CD4 count < 200 cells/mm^1, but no later than 24 weeks. Data from the National Study of HIV in Pregnancy and Childhood (UK and Ireland) suggests that there is an increased risk of transmission in women initiating treatment from 30 weeks gestation, compared to the mean of 26 weeks[8]
- Contributing factors to MTCT include no maternal HIV testing antenatally, poor treatment adherence in pregnancy, late presentation for antenatal care in women with known HIV and postnatal transmission, likely from undisclosed breastfeeding. These factors are often tied in with adverse social circumstances, emphasising the need for multidisciplinary input[9]
- Decisions concerning mode of birth of a pregnant women with HBV/HIV co-infections and HCV/HIV co-infections should be based on standard obstetric and HIV related infections [1]
- There is currently no evidence of increased vertical transmission for multiple pregnancies. Women with multiple pregnancies should be managed according to their obstetric needs

HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PREGNANCY, BIRTH AND POSTPARTUM PERIOD cont'd

- Current adult treatment guidelines strongly recommend antiretroviral therapy for all individuals with HIV at any CD4 cell count; however priority treatment should be initiated in individuals with CD4 cell counts ≤350 cells/mm[1] based on randomised, controlled clinical trial data demonstrating a clear benefit in reduction of mortality and morbidity. Treatment should be initiated in all pregnant and breastfeeding women living with HIV at any CD4 cell count. Women should be counselled about the need to continue therapy after delivery (lifelong) and the importance of adherence to the regimen[1]
- Published cohort data from the UK and other European countries have shown MTCT rates of <0.5% in women with plasma VL <50 HIV RNA copies/ml taking ART, irrespective of mode of delivery. These studies support the practice of recommending planned vaginal delivery for women on ART with plasma VL <50 HIV RNA copies/mL
- Drug interactions are a significant risk. Consult website prior to prescribing, such as MIMs or http://www.hiv-druginteractions.org/Interactions.aspx
- ECV can be offered to women with a breech presentation at ≥ 36 weeks with a VL <50 copies/mL (in the absence of obstetric contraindications)
- There is scant safety evidence to support waterbirth in women living with HIV, however women who choose a waterbirth should be supported to achieve this where the VL is <50 HIV RNA copies/mL
- Undetectable equals Untransmittable (U=U) is a public health campaign that explains how an undetectable viral load is untransmittable with sexual intercourse. While this negates the need for condom use for transmission prevention, safe sex practices to prevent other sexually transmitted infections are recommended[5]

- **Teratogenicity[7,8]:**
  - The prevalence of birth defects among women exposed to any antiretroviral drug is 2.8 per 100 live births[8]
  - Recommended first line treatment is a combination of tenofovir DF/emtricitabine and abacavir/lamivudine
  - British HIV Associations (BHIVA) advises against the combination of tenofovir DF/emtricitabine and lopinavir as it has been associated with an increased risk of neonatal death, predominantly attributed to preterm birth, and severe adverse pregnancy outcomes [2,3]
  - Women on dolutegravir who wish to conceive should be informed of the 0.3% risk for neural tube defect and if choosing to continue, commenced on folic acid 5mg daily. If a woman is already pregnant on dolutegravir, switching is not advised past six weeks gestation[3]
  - Discussion regarding choice of therapy should be made with the woman

- **Contraception:**
  - Due to the induction of liver enzymes, the use of combined oral contraceptive pill, progesterone only pill and progesterone implants (Implanon) may be less effective in those on ART. Nonetheless, there is a role for these methods in conjunction with an additional method
  - The efficacy of depot medroxyprogesterone acetate, levonorgestrel intrauterine system (Mirena) and copper-bearing intrauterine device are not known to be affected by liver enzyme inducers and offer very effective contraception for those on ART
  - A copper-bearing intrauterine device is the recommended method of emergency contraception for women on ART. If progestogen only emergency contraception is used, a doubling of the standard dose to 3mg stat is recommended

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HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PREGNANCY, BIRTH AND POSTPARTUM PERIOD cont'd

- **Breastfeeding[4,5,10,11]:**
  - Formula feeding is still recommended as the safest option
  - Evidence is dependent on well-designed studies held in resource poor countries as there is otherwise a paucity of research outside of these settings. Formula feeding continues to currently remain as the preferred and safer choice for feeding method where good sanitation and clean water is accessible[10]
  - Breastfeeding can be supported only if the mother is adherent to her medication, and breastfeeding remains exclusive up to six months. Mixed (formula and breast) feeding can damage the lining of the infant's gut and increase the risk of contracting HIV and is strongly discouraged. Intensive support and monitoring of the mother and infant are recommended[10,11]
  - ART has reduced MTCT of HIV to virtually zero in industrialised countries. In these countries formula feeding has been strictly recommended. Given the theoretically very low risk of transmission by breastfeeding with ART, and the advantages and benefits of breastfeeding, the strong recommendation to refrain from breastfeeding may no longer be justified[4]
  - Giving women unbiased information on infant feeding, allows for a shared decision making process, allowing for optimal care for mother and her child
  - HIV transmission can never be ruled out even when on effective treatment. Transmission through breastfeeding is in the range of 0.3%-0.9% (for 6-24 months of breastfeeding- the longer the breastfeeding the greater the risk)[4]
  - Within industrialised countries the 'optimal scenario' with virtually zero risk of MTCT is where a woman is 1) adherent to ART 2) under regular care and review 3)has VL< 50 RNA copies/ml throughout pregnancy and breastfeeding

8. RELATED POLICIES / PROCEDURES / CLINICAL PRACTICE LOP

- Sexually transmitted infections / Blood borne viruses antenatal screening and treatment
- Human Immunodeficiency Virus (HIV) in Pregnancy: Prevention of Mother –to-child transmission (RHW/SCH)
- Australian Government Department of Health. Clinical Practice Guidelines, Pregnancy Care. 2019 https://www.health.gov.au/resources/collections/pregnancy-care-guidelines-and-related-documents
- NSW Health, Ending HIV https://www.health.nsw.gov.au/endinghiv/Pages/default.aspx
- Sydney Children's Hospital: Clinical Manual: HIV infection in pregnancy and neonatal diagnosis: A guide to Management
- ASHM Guidelines

9. RISK RATING

- Low

10. NATIONAL STANDARD

- Partnering with consumers – Standard 2
- Comprehensive Care – Standard 5
- Medication Safety – Standard 4

HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PREGNANCY, BIRTH AND POSTPARTUM PERIOD cont'd

11. REFERENCES

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8 Antiretroviral Pregnancy Registry Steering Committee. The Antiretroviral Pregnancy Registry Interim Report for 1 January 1989 through 31 July 2019. Wilmington, NC: Registry Coordinating Center; 2019. Available at http://www.apregistry.com/forms/interim_report.pdf Accessed (April 2020)

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REVISION & APPROVAL HISTORY
Reviewed and endorsed Maternity Services LOPs group 1/6/21
Approved Quality & Patient Safety Committee 21/3/13
Endorsed Obstetrics LOPs group March 2013

FOR REVIEW : JUNE 2026

…./Appendices

APPENDIX 1 : ANTENATAL CARE

WHEN	WHO	INVESTIGATIONS
Pregnancy confirmed	GP / HIV team	Standard pregnancy booking bloods Urine PCR for Chlamydia and gonorrhoea if not previously done Syphilis serology HBcoreAb, HBsAb, HBsAg Cervical Screening if not done in last year Refer for nuchal translucency ultrasound or non-invasive prenatal testing
12-14 weeks	Midwife booking visit Obstetrician visit Discuss immunisation and plan for pregnancy Doctor to write letter (de-identified) regarding care plan- distribute to HIV consultant, SCH team, Access Demand Manager (ADM), CNC infection control, POWH adult ID team HIV status not to be recorded on yellow card Medications will be recorded on yellow card	Check booking bloods/ investigations Nuchal translucency ultrasound or non-invasive prenatal testing at 11-13+ weeks Refer for morphology ultrasound and give referral for 34 week ultrasound
20 weeks	Midwife visit	Review Morphology ultrasound
24 weeks	Midwife visit	Give form for 26-28 week bloods (75g GTT, FBC, antibody screen, +/- repeat Syphilis, Chlamydia, Hep B, Hep C if required). HIV team to order bloods including VL +/- CD4 count
26-28 weeks		Bloods taken as above
28 weeks	Midwife visit Meet with SCH team	Review blood results
30 weeks	Obstetrician visit Consent and book Caesarean section if planned Consent for zidovudine (AZT) and do SSA forms-(patient consent and SSA form to be sent to pharmacy), if required	Review results and plan Arrange AZT to be ready on birthing unit from 34 weeks.
32 weeks	Midwife visit - discuss formula, feeding, tour postnatal ward	
34 weeks	Midwife visit Midwife to email ADM, postnatal manager, Infection control and MUM birthing services Check medication is in birthing unit	Ultrasound- growth HIV team to order VL and FBC at 34-36 weeks gestation,
36 weeks	Midwife visit (weekly) Obstetrician visit – review birth plan	Low Vaginal Swab (GBS) if planning vaginal birth Check bloods including VL
37 weeks	Anaesthetic consult	FBC and G and H day prior to LSCS (if planned)
38-40 weeks	Caesarean section (LSCS) if planned Obstetrician review at 40 weeks re postdates plan	Schedule LSCS to be last on list if zidovudine (AZT) pre-op is required
Postnatal	Dostinex post birth for woman Maternal antiretroviral as per HIV physician – woman to self-administer Notify Pharmacy of birth and neonatal birth weight – they will dispense oral AZT, to be commenced within 4 hours of birth. (Out of hours AZT available via After Hour Nurse Manager (AHNM) from emergency drug cupboard) Paediatrician to prescribe AZT order on baby's medication chart. Delete any eMaternity reference to HIV status before printing discharge summaries.	EDTA HIV PCR blood from baby to be taken before discharge.
Postnatal visit	Woman: 4-6 weeks with midwife or obstetrician Baby: 8 weeks with SCH team	

APPENDIX 2 : ANTE - RETROVIRAL PROPHYLAXIS

TIMING	MOTHER	BABY
ANTENATAL		
Should commence during 2nd trimester (in most cases) and no later than the beginning of the third trimester. Women with high HIV viral load or immunodeficiency (CD4<200 cells/mm3 should start earlier.	ART (with or without zidovudine AZT)	Not applicable (N/A)
INTRAPARTUM Intrapartum intravenous zidovudine (AZT) infusion is recommended in the following circumstances : • For women with a VL of ≥400 HIV RNA copies/mL plasma • For untreated women presenting in labour or with ruptured membranes in whom the current VL is not known • There is data to support the use of intrapartum IV AZT infusion in women with HIV VL > 10 000 copies per ml. There is insufficient information when VL is between 400 and 10 000 copies per ml, and therefore IV AZT is recommended in this group		
ELECTIVE LSCS	If AZT is indicated Commence IV infusion of AZT 3 hours prior to elective Caesarean Section Loading dose : AZT 2 mg/kg IV over 1 hour (dilution = 2 mg/ ml) diluted in normal saline (**refer to appendix 4**) Maintenance dose : Continuous infusion AZT 1 mg/kg/hr until birth.	
WITH ONSET OF LABOUR This is applicable in the following scenarios: Either a) The mode of delivery opted for after counselling is a normal vaginal delivery b) Or spontaneous labour occurs before the date of elective LSCS. AZT should commence in the time interval during the preparation for a semi-urgent caesarean section *(LSCS should not be delayed to complete the intravenous induction course of AZT)*	If AZT is indicated : Commence IV infusion when admitted in labour Loading dose: AZT 2 mg/kg IV over 1 hour (dilution – 2 mg/ ml) (**refer to appendix 4**) Maintenance dose : Continuous infusion AZT 1 mg/kg/hr until birth **NOTE :** • **An untreated woman presenting in labour at term should also have an urgent Infectious disease consultation regarding most appropriate regimen**	
POSTNATAL	**MOTHER**	**BABY**
	Review	**Zidovudine (AZT) Oral** (>34 weeks gestation) 4 mg/kg twice daily (30-34 weeks gestation) 2 mg/kg twice daily for 2 weeks then 2 mg/kg three times a day for 2 weeks (<30 weeks gestation) 2 mg/kg twice daily for 4 weeks **Zidovudine (AZT) Intravenous** (>34 weeks gestation) 1.5 mg/kg four times a day (<34 weeks gestation) 1.5 mg/kg twice daily Refer to Sydney Children Hospital neonatal guidelines if another antiretroviral agent is needed

Appendix 3

FOR MEDICAL RECORD USE ONLY

• MEDICAL RECORD COPY •

South Eastern Sydney Illawarra Area Health Service

CONSENT FOR EXCEPTIONAL USE OF MEDICINE

HOSP ID MRN
SURNAME
OTHER NAMES
DOB SEX AMO

MRN BAR CODE

AFFIX PATIENT IDENTIFICATION LABEL HERE

Exceptional use of medicine includes medication used under the Special Access Scheme (SAS) and some off-label use of a registered medication in an individual patient. See SESIH Area Drug Committee Decision Algorithm for Evaluation of Medicines for Individual Patient Use to confirm justification for exceptional use.

Advice to patient/s carers:

This drug is not registered in Australia for use in the condition listed below which means it has not been evaluated by the Therapeutic Goods Administration of the Australian Department of Health and Ageing, and it may only be considered for exceptional use if an individual patient has a serious underlying disease or condition and standard therapy has been unsuccessful or is inappropriate. There may be unknown side effects. You should discuss the known side effects with the treating doctor before the commencement of treatment. If you have not done this, please ask the treating doctor now to discuss this with you. In addition, should this treatment be ongoing, you should ask the treating doctor whether any new and significant information has become available.

Written informed consent is required prior to treatment with this drug.

Drug name and form: _____

The condition requiring treatment: _____

Alternative therapies that may be considered: _____

_____

Potential risks associated with this treatment: _____

_____

_____

_____

Expected benefits of treatment: _____

_____

_____

Details of additional written material provided: _____

STATEMENT OF CONSENT BY PATIENT

I have read the above information and statement of liability. I understand that by signing this form I am agreeing to accept this liability. I acknowledge that the nature, reason for use, and possible risks of the treatment have been explained to my satisfaction. Before signing this document I have been given the opportunity to ask questions relating to any possible harm I might suffer as a result of the treatment and I have received a satisfactory answer.

Signature of patient/carer: _____ **Date:** ____/____/____

By patient, if over 16 years. Otherwise please state relationship: _____
If adult patient unable to give consent, by guardian/spouse/de-facto/caregiver/Guardianship Board.
If patient between 14-16 years, patient plus parent to sign. If under 14 years, parent or guardian to sign.

I, Prof/Dr _____ ***(Dr name printed),* have fully explained to the patient the nature, purpose and risks of the drug treatment to be employed.**

Signature of authorised prescriber: _____ **Date:** ____/____/____

Admitting Medical Officer (Only for Category A SAS may be AMO's Registrar)

Both signatures witnessed by: _____ ***(Please print name)***

Signature of witness: _____ **Date:** ____/____/____

Original to stay in patient file *Copy to pharmacy with drug order*

S0199 (12/08) NO WRITING AMR 020.250

BINDING MARGIN – DO NOT WRITE

CONSENT FOR EXCEPTIONAL USE OF MEDICINE

Appendix 4

CALCULATION FOR MATERNAL intravenous AZT INFUSION

Dose required: First hour = 2 mg/kg
Second and subsequent hours until delivery = 1 mg/kg/hr

One amp AZT contains 200 mg AZT

Dilute content of one amp in 1000 ml of Normal Saline

= 200 mg AZT in 1000 ml Normal Saline

= 2 mg AZT in 10 ml Normal Saline

= 1 mg AZT in 5 ml Normal Saline

To calculate rate of first hour:

Patient's weight _____kg x 10 = _____ml per hour

To calculate rate for second and subsequent hours until delivery:

Patient's weight_____kg x 5 =_____ml per hour

Divide the above formula by 60 to give rate of infusion in ml per minute.

Examples

For 60 kg patient:
Rate for first hour = 60 kg x 10 = 600 ml per hour Divided by 60 = 10 ml per minute
Half of the above rate for the second and subsequent hours until delivery

For 84 kg patient:
Rate for first hour = 84 kg x 10 = 840 ml per hour Divided by 60 = 14 ml per minute
Half of the above rate for the second and subsequent hour until delivery

Appendix 5

Breastfeeding

Information for Mothers with HIV

Updated: April 2021

Background

Formula feeding is the safest way for a mother with HIV to feed her baby. In Australia formula feeding is very common. We understand that there is a lot to consider when deciding how to feed your baby. This leaflet aims to provide you with information to help you make an informed decision about how to feed your baby.

Breastfeeding or Formula Feeding?

In Australia the National Health and Medical Research Council (NHMRC) advises women who are HIV positive not to breastfeed. Passing HIV through breastmilk to your baby is well documented (this is known as vertical transmission). The levels of virus within breastmilk can go up and down and even be different between breasts. In countries where there is clean water and affordable formula - formula feeding is recommended as there is no risk of passing HIV onto your baby. The risk of the baby being infected with HIV through breastmilk in women who are on antiretroviral therapy and have an undetectable viral load is estimated 3 in 1000 at 6 months when fully breastfed*.

If you are on treatment with an undetectable viral load, you and your baby do not have any stomach bugs, your breasts and nipples are healthy, and you choose to breastfeed, we can support and help you make this as safe as possible. Together we can reduce the risk of passing HIV to your baby by using 'The Safer Triangle' model.

The Safer Triangle

No Virus

HIV virus in your blood reflects HIV in your breast milk which can be passed to the baby. If there are detectable levels of HIV in your blood, stop breastfeeding and use formula milk. Throw away any expressed breastmilk.

Healthy Breasts for Mums

If your nipples are cracked, bleeding or if you have thrush or any breast infection there may be HIV in your breastmilk. Stop breastfeeding. Bottle feed with formula or milk that was expressed more than 48 hours before the infection or bleeding. If you feed the baby with expressed breast milk, you can restart breastfeeding 48 hours after your breasts are healed. Once you start formula you need to keep formula feeding only

Happy Tums

Your baby may experience diarrhoea or vomiting if he or she has an irritated tummy. HIV is more likely to cross into your baby's blood stream and cause infection. If you have an upset tummy, you may not absorb your medications properly. Only breastfeed if you and your baby both have 'happy tums'. You can bottle feed with formula or breastmilk expressed at least 48 hours before your tummy problems started. Consult your HIV team before restarting breastfeeding.

The Safer Triangle means "No Virus + Happy Tums + Healthy Breasts for Mums"

Adapted from British HIV Association *HIV and breastfeeding your Baby* patient information leaflet 1 *Is breastfeeding and equipoise option in effectively treated HIV-infected mothers in a high-income setting? Swiss Medical Weekly. 2018

Breastfeeding

Information for Mothers with HIV

Updated: April 2021

Protect Your Baby While Breastfeeding

Some simple ways you can use to minimise the risk of HIV passing onto your baby:

♦ Taking your medications daily	Medications will help to suppress the VL in your bloodstream making it safer to breastfeed. Your medication can get into the breastmilkbut are unlikely to hurt your baby. If your baby does become infected with HIV, there is a possibility that the medication you are taking may not work for your baby
♦ Breastmilk only	Choosing to feed with breastmilk only is called 'exclusive' breastfeeding. This is much safer than mixed feeding, where you top-up feeds with formula. Mixed feeding can irritate your baby's tummy and double the risk of infection with HIV. We recommend changing to formula feeding when you have reached a maximum of 6 months of exclusive breastfeeding or when your baby is about to start solids (whichever comes first)
♦ Limit how long you breastfeed	Studies show that babies who are breastfed from mums with HIV for 12 months are twice as likely to become infected, than those breastfed for 6 months. Think about and decide at what point you will feel happy changing to formula feeds
♦ Keep in touch with your specialist team	Breastfeeding can be hard for any mum. A little extra planning is required for mums living with HIV. If you have any questions or run into problems during your breastfeeds, we encourage you to speak with your HIV team. We are here to support and help you.

Helpful Resources

⇒ The Paediatric HIV Service at Sydney Children's Hospital, Randwick http://www.schn.health.nsw.gov.au/find-a-service/health-medical-services/immune-deficiency-and-hiv/sch Enquiries: 02 9382 1508. Clinical Nurse Consultant: 02 9382 1654. Social Worker 02 9382 1851

⇒ Australian Breastfeeding Association: www.breastfeeding.asn.au 1800 686 268

⇒ Living Well Website: www.womenlivingwell.org.au/having-children/

⇒ Mother safe – Medications in Pregnancy & Lactation: https://www.royalwomen.org.au/mothersafe 02 9382 6539

⇒ Private Lactation Consultants: www.lcanz.org

⇒ NSW Health: www.health.nsw.gov.au/Infectious/factsheets/Pages/HIV-infection.aspx

⇒ Formula feeding for a neonate:

https://www.seslhd.health.nsw.gov.au/sites/default/files/documents/formulafeed19.pdf

⇒ National Association of People with HIV Australia http://napwha.org.au

Adapted from British HIV Association *HIV and breastfeeding your Baby* patient information leaflet 1