Medication Management
Clinical Practice Guidelines

TITLE:	Perinatal Human Immunodeficiency Virus (HIV) Transmission Prophylaxis	**NUMBER:**	80.26
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PREAMBLE

HIV transmission from parent to child can occur in utero, intrapartum and through breastfeeding, with most transmissions occurring late in pregnancy or around the time of birth. With effective antiretroviral treatment for the pregnant person, during labour and for the neonate after birth, the transmission rate of perinatal HIV infection has been reduced from 25-30% to less than 2%. The risk of a breastfeeding infant acquiring HIV from a parent with HIV is 15% to 20% over 2 years in the absence of antiretroviral therapy.

This policy outlines recommendations for the early identification of HIV infection during pregnancy, the management of people living with HIV during pregnancy, and the intrapartum and postpartum management of people living with HIV or people at high-risk for HIV infection and their infants.

POLICY STATEMENTS

1. People living with HIV will be counselled on and offered antepartum, intrapartum and neonatal prophylactic treatment for prevention of perinatal transmission.

2. IWK Health will follow the most recent recommendations for use of antiretroviral drugs in pregnant people living with HIV and interventions to reduce perinatal HIV transmission.

3. All pregnant people living with HIV will be referred to the IWK Health Pediatric Infectious Disease team for counselling regarding neonatal prophylactic treatment, infant feeding recommendations and follow-up.

4. **Initiation of antiretroviral therapy will be made in collaboration with Infectious disease consultants at the QEII Health Sciences Centre and IWK Health Infectious Disease teams**

5. Routine practices must be used with all patients to reduce the transmission of microorganisms in all health care settings. (refer to IWK Policy 201.1 – Application of Routine Practices). Additional precautions are not required for patients on the basis of HIV status alone.

GUIDING PRINCIPLES AND VALUES

1. Privacy and confidentiality of parental and infant HIV status must be ensured (refer to IWK Health Policy #333- Privacy of Personal Health Information and Privacy Complaints Process.)

2. IWK Health holds Baby Friendly Initiative (BFI) designation. Standard BFI care recommendations should be followed for all infants, including those born to parents living with HIV.

3. In Canada, the safest way to feed infants born to a person living with HIV is with formula, as breastfeeding presents an ongoing risk of HIV transmission after birth., ARV therapy significantly reduces, but does not eliminate, the risk of transmitting HIV through breastfeeding even with undetectable viral load. In addition, there is limited data on the safety of most modern ARV regimens during breastfeeding.

PROCEDURE

Antepartum

1. Screening and Testing

1.1 Counseling should be performed and informed consent should be obtained **prior** to testing.

1.2 HIV testing should be offered to all pregnant people, regardless of real or perceived risk factors (See Appendix B) and irrespective of prior HIV testing, early in pregnancy. Retesting in the third trimester is recommended for pregnant people who initially test negative but have ongoing risk factors for HIV acquisition.

1.3 If the person has an unknown HIV status prior to the onset of labor, HIV testing should be performed.

1.4 In addition to HIV screening, all pregnant people should be tested for antibodies to rubella, hepatitis B, hepatitis C, and syphilis during early pregnancy

2. **Initial evaluation**

2.1 Assess the person's HIV disease status including CD4 count, viral load, and antiviral drug-resistance testing in the case of detectable viremia (i.e. HIV RNA levels greater than 500-1000 copies/mL).

2.1.1 Resistance testing results can be used as a guide for starting or modifying antiretroviral drug regimens. Patients presenting late in pregnancy should begin antiretroviral treatment immediately, without waiting for resistance testing results. Adjustments can be made as needed after these test results are available.

2.2 The obstetrical team, in collaboration with Adult ID will assess the person's current antiretroviral (ARV) therapy. This includes type, dose, and adherence to therapy. The regimen in place may need to be altered during pregnancy.

2.2.1 Effective ARV therapy with undetectable viral load is optimal prior to any prenatal invasive diagnostic procedures to minimize risk of HIV transmission to the fetus. For details regarding maternal and fetal monitoring during pregnancy visit the Clinician info HIV website.

3. Care Planning

3.1 Referral of the pregnant person living with HIV to the Maternal Fetal Medicine Clinic is recommended as soon as possible during pregnancy.

3.2 The obstetrical care provider will ensure the NS Health HIV clinic is aware that the patient is pregnant and being followed for prenatal care.

3.3 The obstetrical team will notify a clinical nurse specialist (CNS) and clinical pharmacist from the Women's & Newborn Health Program (WNHP) when a person with HIV is seen at their first point of prenatal care.

3.3.1 The pharmacist will review the person's home ARV regimen and obtain the Best Possible Medication History.

3.3.2 The pharmacist will instruct the person to bring their medications in the original containers to be used during admission. **These medications are not routinely stocked or on formulary**.

3.3.3 A complex care plan is developed by the CNS and scanned to the patient's permanent health record.

3.4 Consider bloodwork to measure viral load between 34-36 weeks to assist with birth planning.

4. Infant Feeding Planning

4.1 Breastfeeding is **not recommended** for any person living with HIV in Canada because of the risk of HIV transmission through breast milk. This recommendation also applies to people receiving combined Antiretroviral Therapy (ARV) and those with an undetectable viral load.

4.1.1 Concerns about this recommendation and the "Acceptable/Feasible/Affordable/Sustainable/Safe" (AFASS) criteria (Appendix C) should be addressed as early as possible during the pregnancy and no later than the dyad's discharge from hospital.

4.2 Infant feeding planning, including the recommendation to formula feed, should occur with all pregnant people living with HIV early in their pregnancy. This discussion must involve the Pediatric Infectious Disease Team and include the following:

- Risk of HIV transmission from breastfeeding
- Rationale for formula feeding recommendation
- An evaluation of AFASS (Appendix C) criteria for the family
- Concerns parents may have related to social and cultural expectations to breastfeed, including how to explain their choice to bottle feed without disclosing their HIV status.

4.3 If people living with HIV choose to breastfeed after the infant feeding discussion, it is important to clarify their understanding of the risks of HIV transmission via breast milk and to determine the reasons for them choosing to breastfeed. They should then be counseled to use harm-reduction measures to minimize the risk of HIV transmission

to their infants (See Appendix D). Automatic referral to child protection services is not warranted. (**Please note this is not intended to be an endorsement of breastfeeding, nor to imply that breastfeeding is recommended for people with HIV in Canada**.)

4.4 Any discussion about infant feeding should be documented in the permanent health record.

5 Antiretroviral (ARV) Therapy

5.1 Combination antiretroviral (ARV) drug therapy with **at least three** antiretroviral drugs is recommended for all pregnant people living with HIV.

5.1.1 The initiation and choice of ARV regimen depends on many factors (e.g. maternal health status, HIV RNA levels, CD4-count and the presence of pregnancy-related complications such as nausea and vomiting, current adult treatment guidelines, resistance testing, transplacental passage, teratogenicity, potential drug adverse effects, past antiretroviral drug use) and must be individualized for each pregnant person.

Intrapartum

1. **Admission**

1.1 Complete clinical order set IWK_HIVIP for all pregnant people living with HIV regardless of HIV viral load and prenatal ARV therapy OR for pregnant people with unknown status and risk factors for HIV infection

1.2 Notify Pharmacy of patient's admission for verification of their home medications as per IWK Policy 3.90 Medications Brought into Hospital by Patients

1.3 Notify IWK Pediatric Infectious Disease team when the pregnant person living with HIV is admitted for labour and birth.

2. **Planning for Birth**

2.1. Unless contraindicated by other health reasons:

2.1.1. Cesarean birth is recommended for HIV viral loads greater than 1000 copies/mL

2.1.2. Vaginal birth is recommended for HIV viral loads less than 1000 copies/mL

2.2. Pregnant people living with HIV should be informed of the risks associated with cesarean births, and these potential risks balanced against the potential benefits for the child.

2.2.1. While there is likely little added reduction in HIV transmission risk during a cesarean birth in people with undetectable viral loads, the potential benefits versus risks of cesarean delivery should be discussed with an infectious disease specialist when the viral load is detectable but below 1000 copies/mL.

2.2.2. The recommended timing of cesarean birth depends on the indication:

2.2.2.1. at 38 weeks gestation when performed for HIV viral load greater than 1000 copies/mL
2.2.2.2. at 39 weeks gestation when performed for standard obstetrical indications (e.g. repeat cesarean, breech, etc).
2.2.3. Standard procedures for patients undergoing cesarean births, such as prophylactic antibiotics at the time of cesarean delivery, should also be followed with people living with HIV.

2.3. The following intrapartum procedures should be avoided unless there is a clear obstetrical indication:
2.3.1. artificial or prolonged rupture of membranes,
2.3.2. routine use of fetal scalp electrodes,
2.3.3. intrauterine pressure catheter
2.3.4. assisted birth (forceps, vacuum, or episiotomy)

3. Antiretroviral (ARV) therapy

3.1. Follow direction for ARV therapy on preprinted order IWK_HIVINF.
3.2. The decision to treat with intrapartum zidovudine should not be made based on viral load close to birth. All people living with HIV, regardless of viral load, should receive intrapartum zidovudine as per preprinted order IWK_HIVINF.
3.3. Pregnant people with unknown HIV status and risk factors for HIV infection can discontinue intravenous zidovudine once a negative HIV test result is obtained prior to delivery.
3.4. People taking oral zidovudine as part of the antepartum ARV regimen, should stop the oral form while receiving IV zidovudine. Continue all other ARV medications during labour.

Postpartum (Birth Parent)

1. Care Planning

1.1 People diagnosed with HIV in the intra- or postpartum period should be referred to Adult Infectious Diseases for HIV care and comprehensive follow up before discharge from the hospital.

2. Breastfeeding/Feeding

2.1 Breastfeeding is **not recommended** for any person living with HIV in Canada because of the risk of HIV transmission through breast milk. See Antepartum Infant Feeding Planning above and Appendix C & D for further information.
2.2 Cabergoline may be offered as per HIV Postpartum preprinted order IWK_HIVIP to manage breast engorgement if needed.

3. Antiretroviral (ARV) therapy

3.1 Ensure preprinted order IWK_HIVIP has been completed for all people living with HIV regardless of HIV viral load and prenatal ARV therapy.

3.2 Following birth, the decision to continue or change the person's ARV treatment should be made in conjunction with obstetrical care and Adult Infectious Diseases. Ideally, this decision is made prior to the person's discharge from hospital so that arrangements can be made for additional support for medication adherence during the postpartum period.

Postpartum (Infant)

1. Initial care

1.1. As soon as birth weight has been determined, complete the HIV Infant/Newborn Orders Clinical order set IWK_HIVINF.

1.2. If not already done, notify the IWK Pediatric Infectious Disease team that the infant has been born. The team should also be consulted for guidance on:

1.2.1. testing and management of infants born to a person with unknown or suspected positive HIV status.

1.2.2. management of infants born to a person living with zidovudine drug-resistant HIV virus

1.3. Infants born to a person living with HIV do not require additional monitoring or precautions, unless required for other clinical indications.

2. Antiretroviral (ARV) prophylaxis

2.1. The decision to initiate ARV therapy should be made prior to birth with the IWK Pediatric Infectious Diseases team and should take into account potential risks and benefits to the neonate.

2.2. Orders for the COMPLETE course of infant ARV medications are obtained from the attending newborn care provider after birth.

2.3. The full medication bottle should be removed from Birth Unit Pyxis for the infant's first dose of the ordered ARV medication(s). When pharmacy is open, the medication bottle(s) should be sent to IWK Main Pharmacy for relabeling with dosage instructions. The Clinical Pharmacist should be paged if available. When not available, the main pharmacy should be contacted and leave a voice mail in main dispensary.

2.4. IWK Main Pharmacy will send the relabeled medication bottle(s) to the unit. **The IWK nursing staff provides the COMPLETE 6 week supply of medication(s) to the infant caregiver prior to discharge.**

2.5. Discharge Medication Reconciliation Form or Meditech generated discharge prescription should be completed indicating discharge medications, including volume supplied, and that the supply was dispensed by IWK Pharmacy.

2.6. Have Clinical Pharmacist counsel family on administration of ARV medication(s) and ensure relevant infant drug information handouts are given to caregiver (see related documents)

2.7. Infants born to a person with unknown HIV status and risk factors for HIV infection (see Appendix B) can discontinue zidovudine once a negative parental HIV test result is obtained and there is low likelihood of a recent infection.

3. Administer Hepatitis B vaccine as per Policy 20.13 Newborn Hepatitis B Immune Globulin & Vaccine Prophylaxis Schedule

REFERENCES

IMCI Complementary Course on HIV/AIDS; Module 3: Counselling the HIV Positive Mother. WHO 2007

Levinson J, Weber S, Cohan D (2014). Breastfeeding and HIV-infected women in the United States: Harm reduction counseling strategies. *Clinical Infectious Diseases 59*(2), 304-309. Doi: 10.1093/cid/ciu272

Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1 Infected Women for Maternal Health and Interventions to Reduce Perinatal Transmission in the United States. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf Accessed 5 May 2021.

Prevention of Perinatal Transmission BC Women's Hospital and Health Centre. Available here

UNAIDS Terminology Guidelines (2015). Joint United Nations Programme on HIV/AIDS. Available at: UNAIDS Terminology Guidelines – 2015

World Health Organization (2013). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: Recommendations for a public health approach. Retrieved from: https://apps.who.int/iris/bitstream/handle/10665/85321/9789241505727_eng.pdf;jsessionid=23ACF804063575C76156579BD15D27CF?sequence=1

World Health Organization (2016). Guideline: Updates on HIV and infant feeding. Retrieved from: http://apps.who.int/iris/bitstream/handle/10665/246260/9789241549707-eng.pdf?sequence=1

RELATED DOCUMENTS

Policies

IWK Health Policy 201.1 – Application of Routine Practices
IWK Health Centre Policy #333- Privacy of Personal Health Information and Privacy Complaints Process.
IWK Health Policy 3.90 – Medications Brought into Hospital by Patients
IWK Health Policy 1.40 – Formulary Policy
IWK Health Policy 80.28 – Newborn Hepatitis B Immune Globulin & Vaccine Prophylaxis Schedule.

Forms

IWK_HIVIP- Intrapartum and Postpartum HIV Orders
IWK_HIVINF- HIV Infant orders
IWK_HEIM – Hepatitis B (HB) Immunization Orders

Other

Zidovudine Information Sheet
Lamivudine Information Sheet
Nevirapine Information Sheet

APPENDIX A – DEFINITIONS

AFASS Criteria: The acronym 'AFASS' - Acceptable, Feasible, Affordable, Sustainable and Safe – helps health care providers and families to think about the specific conditions that are needed if replacement feeds are to be given safely to infants. These include safe water and sanitation, continuity of adequate supplies, ability to prepare and give it safely, family support and availability of health care. All of these conditions need to be taken into account when recommending the most appropriate infant feeding practices.

Person living with HIV: The preferred term for someone who is HIV-positive (or seropositive) and has had antibodies against HIV detected in a blood test or gingival exudate test (commonly known as a saliva test).

Viral Load: The amount of HIV in a sample of blood. Viral load is reported as the number of HIV RNA copies per milliliter of blood. An important goal of antiretroviral therapy is to suppress a person's viral load to an undetectable level—a level too low for the virus to be detected by a viral load test.

APPENDIX B – RISK FACTORS FOR HIV

Risk factors for HIV include, but are not limited to:

- Acute febrile illness consistent with acute HIV infection (e.g. EBV negative mono-like illness)
- injection drug use,
- From a population with a high prevalence of HIV (e.g. recent incarceration or from an country where HIV is endemic)
- hepatitis B and/or C positive status,
- diagnosis of a sexually transmitted infection during pregnancy,
- sex with multiple partners,
- unprotected sex with an HIV-infected or high-risk partner(s).

APPENDIX C – AFASS CRITERIA

All pregnant people living with HIV should receive counseling on infant feeding options as part of their care, in order to reduce the risk of transmission of HIV to their child during breastfeeding. When replacement feeding meets the AFASS criteria below, avoiding breastfeeding is recommended. Otherwise, exclusive breastfeeding is recommended during the first 6 months of life.

AFASS Criteria (WHO 2007)
Acceptable: The parent perceives no problem in replacement feeding. Problems may be cultural or social, or be due to fear of stigma and discrimination. **Feasible:** The parent (or family) has adequate time, knowledge, skills, resources, and support to correctly mix formula or milk and feed the infant up to 12 times in 24 hours. **Affordable:** The parent and family, with community or health system support if necessary, can pay the cost of replacement feeding without harming the health and nutrition of the family. **Sustainable:** Availability of a continuous supply of all ingredients needed for safe replacement feeding for up to one year of age or longer. **Safe**: Replacement foods are correctly and hygienically prepared and stored, and fed preferably by cup

APPENDIX D – HARM REDUCTION STRATEGIES WHEN BREASTFEEDING WITH HIV

If people living with HIV choose to breastfeed after discussions with their health care provider including the Pediatric Infectious Disease team, it is important to clarify their understanding of the risks of HIV transmission via breast milk and to determine the reasons for them choosing to breastfeed. They should then be counseled to use harm-reduction measures to minimize the risk of HIV transmission to their infants.

The harm reduction model suggests that “people will make more health-positive choices if they have access to adequate support, empowerment, and education”.

In regards to breastfeeding with HIV, harm reduction measures include, but are not limited to:

- Health care providers engage in all conversations with an open, empathetic approach. Some people living with HIV may choose to breastfeed without telling their health care provider if they fear stigma, judgment, or criminalization
- Exclusively breastfeed for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast-milk can be provided.
- Ensure access to ARV therapy for the period of breastfeeding regardless of the person’s CD4 count or clinical stage, and monitor viral load throughout the duration of breastfeeding
- Provide counselling to the person about the importance of adherence to their ARV regime. The risk of HIV transmission is lower, **though still not eliminated**, when the breastfeeding person has an undetectable viral load.
- Involve a lactation consultant early in the postpartum period to facilitate optimal latching at breast and avoid nipple damage.
- Flash heat treatment of expressed breast milk, when done correctly, has been demonstrated to inactivate the effectivity of HIV and may be feasible and acceptable for some people living with HIV.

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IWK Policies Being Replaced

Version History

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
	October 20, 2016
	September 2017
December 2020 (additional information harm reduction breastfeeding, updated links)	
May 2021	