Guidelines for the Prevention of Mother-to-Child HIV Transmission

Information and Practice Guidance for Health Practitioners in Ontario: Working with HIV-infected Women with Inadequate Control of HIV, and Women with Unknown HIV Status Who Present in Labor

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The focus of this document is to provide suggested management of mother-infant pairs where:

(a) The mother is known to be HIV-infected, but has not (or suspected to have not) achieved complete virologic suppression late in gestation (near the time of delivery) or;

(b) The mother's HIV status is not known at presentation in labor.

HIV Program personnel across Ontario are available 24/7 to provide telephone advice regarding management of any HIV-infected pregnant woman or any pregnant woman at high risk of HIV infection with respect to prevention of perinatal HIV transmission as well as the management and follow-up of their infants.

Contact information for selected Obstetricians and Pediatricians with HIV expertise is provided. The contact information for clinic coordinators in clinics providing HIV care to adults is also given. It is not possible to list all the physicians that provide HIV care to adults – for advice it is recommended that a local expert be contacted.

These guidelines were developed with the support of health care practitioners and clinicians from across Ontario. Thanks for their time and constructive feedback.

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Contact information for HIV experts in the prevention of Mother-to-Child-transmission of HIV in Ontario.

Obstetrics and Gynecology

- Kellie Murphy, MD, Mount Sinai Hospital, Toronto
  Telephone: 416-586-8570
  Email: kmurphy@mtsinai.on.ca
  After hours, on weekends contact the Maternal-Fetal Medicine specialist on call via 416 586 5133

- Mark Yudin, MD, St. Michael's Hospital, Toronto
  Telephone: 416-864-3078
  Email: YudinM@smh.ca
  After hours, on weekends contact the Obstetrical staff on call via 416-864-5431

Pediatric HIV Care Providers

1. Toronto:
   - Georgina MacDougall, RN, Clinic Coordinator, Hospital for Sick Children
     Telephone: 416 813 7444
     Email: georgina.macdougall@sickkids.ca

   - Sean Ari Bitnun, MD, Hospital for Sick Children
     Telephone: 416 813 7654 ext 206268
     Email: ari.bitnun@sickkids.ca

   - Stanley Read, MD, Clinic Director, Hospital for Sick Children
     Telephone: 416 813 7654 ext 206268
     Email: stanley.read@sickkids.ca

   - After hours, on weekends contact the Infectious Diseases fellow on call via 416 813 7500

2. Ottawa:
   - Evelyn Marquis, RN, Clinic Coordinator, Children's Hospital of Eastern Ontario
     Telephone: 613 737 7600 ext 2543
     Email: emarquis@cheo.on.ca

   - Jason Brophy, MD, Clinic Director, Children's Hospital of Eastern Ontario
     Telephone: 613 767 7600 ext 2651
     Email: JBrophy@cheo.on.ca

- Lindy Samson, MD, Children's Hospital of Eastern Ontario
  Telephone: 613 767 7600 ext 2606
  Email: Samson@cheo.on.ca

- After hours, on weekends contact the Infectious Diseases physician on call via 613 737 7600

3. Hamilton:
   - Sandi Seigel, MD, SIS Clinic, McMaster Children's Hospital
     Telephone: 905-521-5030
     Email: seigels@mcmaster.ca

   - Sarah Khan, MD, SIS Clinic, McMaster Children's Hospital
     Telephone:905-521-2100 ext 77577
     Email: khan259@mcmaster.ca

   - After hours, on weekends contact the Infectious Diseases Physician on call at 905-521-2100

Adult HIV Care Providers (HIV Clinic Coordinators)

(See Appendix 1: Ontario HIV Outpatient Clinic Coordinator / Director Network - Contact Information)

General Principles of Management

1. Infection prevention and control:

    - Standard universal blood and fluid precautions should be observed in the management of mother infant pairs. Additional precautions are NOT required.
    - Newborn infants should be washed with soap and water to remove maternal blood and amniotic fluid prior to intramuscular injections or blood sampling.

2. Exclusive formula feeding is currently recommended for infants born to mothers living with HIV in Canada irrespective of maternal clinical, immunologic and virologic status or antiretroviral therapy (ART) received. Health care providers must ensure the mother is aware of the provincial Ministry of Health and Long-term care free formula program for infants born to women living with HIV which is managed by the Teresa Group and facilitate enrolment in the program (416 596 7703).

3. Ensure confidentiality of maternal and infant HIV status at all times throughout the prenatal, labour, delivery and postnatal care.

4. Women should be referred for consultation to a pediatric HIV clinic prior to delivery so that they can meet the pediatric team and:

    - Discuss the proposed infant management, follow-up and testing protocol
    - Discuss infant feeding recommendations
    - Identify any factors that might increase the risk of perinatal HIV transmission and discuss these with the obstetrical and adult HIV care providers
    - Recommend appropriate interventions and receive general counseling regarding transmission and other risks to the infant
    - Discuss future care of her child

5. Consultation with the pediatric HIV team at one of the pediatric HIV centers listed above is recommended for all infants where the mother is known to be HIV positive or considered to be at high risk of being HIV positive once the baby is born.

6. The pediatric HIV clinic coordinator for your region should be contacted following delivery. The baby's birth record, mom's prenatal and delivery record including viral load, CD4 count, maternal and infant antiretroviral regimens as well as the baby's CBC and differential results should be faxed to the pediatric HIV referral center where the baby is to be followed as per local protocols.

7. All infants born to HIV infected women as well as those born to women of unknown HIV status who are considered to be at increased risk of HIV infection (history of ongoing or recent intravenous drug use, commercial sex work, unprotected sex with multiple partners, recent immigration from high prevalence regions of the world, etc) **in whom interventions were put in place to try and decrease perinatal transmission of HIV** should be referred for follow-up in a clinic that specializes in pediatric HIV care. The

timing of the first follow-up appointment should be discussed with the pediatric HIV clinic coordinator, but should take place no later than 4 weeks of age.

Testing for HIV in pregnant women with unknown HIV status

1. HIV testing, after appropriate pre-test counseling, is recommended for all pregnant women in each pregnancy irrespective of prior HIV testing unless known to be HIV positive already. Retesting in the third trimester is indicated for women considered at higher risk of HIV infection.

2. HIV test results should be given to the woman in person, with appropriate post-test counseling.

3. All women testing HIV positive should be referred immediately to an adult HIV care provider.

4. Health care provider consultation with an obstetrician with expertise in caring for women living with HIV should be considered if they are not familiar with the standards of care and monitoring during such pregnancies.

5. The results of HIV testing (serology and if positive, viral load, genotypic resistance testing) should be provided to the institution where a pregnant woman is scheduled to be admitted for labor and delivery in a timely manner (prior to the onset of labor) so that health care professionals involved in her care are aware of her HIV testing/result status. Confidentiality of this information must be maintained.

6. STAT HIV testing should be offered to all women presenting in labor for whom HIV test results from the current pregnancy are not known:
    a. STAT HIV serology should be considered for all such women. To order STAT HIV testing:
        1. During regular working hours – contact the local Public Health Ontario Laboratory (PHOL) or your local laboratory, if licensed to conduct HIV screen testing in high risk women in labor);
        2. During evenings and weekends – approval is required from the duty officer and medical microbiologist on call at PHOL (telephone number: 416-605-3113)
    b. STAT HIV-1 PCR or viral load testing may be considered on an individual basis in consultation with an HIV expert to detect very recent HIV infection that could be missed by serology (window period). See item B1b on page 14 for additional details.

Testing for HIV infection and monitoring for toxicity in infants born to mothers with HIV infection or to mothers considered to be at high risk of HIV infection

1. Newborn samples
    a. HIV-1 PCR and HIV serology within 48 hours of birth (Appendix 2).
        - The sample should consist of 2-3 ml of blood in EDTA tube (lavender top).
        - Blood to be processed within 12 hours of collection.
        - If delivery on weekend please draw the blood as close to Monday morning as possible before discharge. If sample processing cannot be completed within 12 hours it should be refrigerated pending transport (4.0^0C). Please hold specimen until it can be delivered on Monday morning.
        - HIV-1 PCR testing is performed at PHOL, Toronto
        - Specimens should be delivered to the local lab responsible for processing of samples in your area or directly to PHOL, Toronto
            - Toronto: Dr. Stanley Read's laboratory located on the 7th floor, Elm wing at the Hospital for Sick Children (room 7314); lab hours are 0900 to 1500 Monday through Friday
            - Ottawa: Eastern Ontario Regional Virology Laboratory, CHEO, 401 Smyth Road, Ottawa ON K1H8L1; lab hours are 0800 to 1530 (sample should reach the lab prior to 1400 to allow sufficient time for processing)
            - Other sites should refer samples directly to PHOL
        - HIV-1 PCR testing can also be performed on dried blood spot samples. This may be most appropriate for infants born in remote communities or on weekends. For details of such testing please contact PHOL (Appendix 2).
    b. A complete blood count and differential
    c. Baseline liver enzymes and serum lactate should be considered

    ****NB Antiretroviral therapy can be initiated prior to blood sampling of the infant for HIV-1 PCR.**

2. Testing for hepatitis B and syphilis should be done in cases where maternal status is not known; testing should include hepatitis B surface antigen (HBsAg), hepatitis B core antibody (HBcAb), hepatitis B surface antibody (HBsAb) and standard syphilis testing. Serology for hepatitis C virus (HCV) should also be sent in women of unknown status with risk factors for infection.

3. In addition to the birth HIV-1 PCR, two additional HIV-1 PCR assays should be performed at 1 month of age or later for all infants. In some centers such testing is done at 1 and 2 months of age; in others between 1-2 and 4-6 months of age.

    Infants who received triple combination antiretroviral therapy (cART) during the neonatal period are recommended to have additional HIV testing. HIV-1 PCR should be done at 2 weeks of age in order to facilitate treatment decisions at 4 weeks of life (the sensitivity of HIV-1 PCR at 2 weeks is ≥ 90%). In addition, such children should have at

least one test performed ≥ 2-4 weeks after stopping combination antiretroviral therapy, assuming all prior tests were negative.

4. Complete blood count with differential, ALT and serum lactate with each PCR test.

5. For newborn infants placed on nevirapine-based combination antiretroviral therapy (cART), trough nevirapine levels in serum should be measured 7 days and 14 days after starting nevirapine therapy and the nevirapine dose adjusted as required in consultation with a clinician and/or pharmacist familiar with antiretroviral medications and pediatric dosing. Involvement of a Pediatric HIV specialist is recommended for all newborns placed on cART. The sample for measurement of nevirapine serum level should consist of 1.0 ml of blood in a heparinized tube (green top).

6. HIV serology at 18 – 24 months of age to document loss of transplacental maternal antibody.

Clinical Scenario-Specific Management

The following scenarios have been grouped into 2 categories:

A. Pregnant women with documented HIV infection seen late in gestation (≥ 34 weeks) or, if earlier in gestation, at the time of preterm labor onset and

B. Pregnant women with unknown or undocumented HIV status who present in labor.

The scenarios described are meant to capture the most common situations faced by clinicians with the purpose of providing guidance in management. It is recognized that some clinical scenarios may not correspond exactly to those described; consultation with an adult and a pediatric HIV specialist as well as an Obstetrician with expertise in HIV care is indicated.

A. Pregnant women with documented HIV infection (see Table 3 for specific suggested interventions)

1. Women with known HIV infection treated with cART beginning before conception or, if after conception, before week 34 of gestation, who are clinically well and whose most recent viral load was documented to be undetectable (< 40 copies/mL or target not detected)
    a. Intravenous Zidovudine during labor until delivery
    b. Cesarean section is **not** routinely recommended in this scenario
    c. Zidovudine prophylaxis for 4-6 weeks for the infant. For full-term infants, 4 weeks of zidovudine prophylaxis is recommended if the mother had received cART during pregnancy, had sustained viral suppression and there were no concerns related to maternal adherence. In other circumstances a 6 week course is recommended, although in selected cases it may be reasonable to give only 4 weeks (e.g. significant anemia attributable to zidovudine).

2. Women with known HIV infection treated with cART beginning before conception or, if after conception, before week 34 of gestation, who are clinically well and whose most recent viral load was documented to be detectable, but less than 1000 copies/mL
    a. Involvement of an adult and a pediatric HIV specialist as well as an Obstetrician with expertise in HIV is recommended
    b. Intravenous Zidovudine during labor until delivery
    c. Vaginal birth is usually recommended. However, elective Cesarean section may be considered on an individual basis. The potential benefit of elective Cesarean section in further reducing the risk of HIV transmission and the potential adverse effects of elective Cesarean section should be discussed with the woman; this discussion should take place well in advance of the expected Cesarean section date.
    d. Combination ART for the infant should be considered (see Table 2 and 3); Zidovudine monotherapy may still be appropriate in these situations, particularly

if an elective Cesarean section is performed. Urgent consultation with a specialist in pediatric HIV is indicated for all cases.

e. In the situation where cART is recommended for the infant, zidovudine, lamivudine and nevirapine is the preferred regimen. When there is documented non-nucleoside reverse transcriptase inhibitor (nevirapine) resistance in the mother, raltegravir-based infant cART is the preferred treatment option (instead of nevirapine-based cART). Raltegravir granules for oral suspension are currently only available through Health Canada's Special Access Program.

3. Women with known and inadequately controlled HIV as defined by a recent viral load greater than 1000 copies/mL irrespective of antiretroviral therapy duration and type
    a. Involvement of an adult and a pediatric HIV specialists as well as an Obstetrician with expertise in HIV is recommended
    b. Combination ART for the woman should be initiated if not already done; integrase strand transfer inhibitor (INSTI)-based cART should be considered when treatment is started in the third trimester.
    c. Intravenous Zidovudine during labor until delivery
    d. Elective Cesarean section should be recommended unless contraindicated for maternal health reasons. The potential benefit of elective Cesarean section in further reducing the risk of HIV transmission and the potential adverse effects of elective Cesarean section should be discussed; this discussion should take place well in advance of the expected Cesarean section date.
    e. Combination ART is indicated for the infant (see Table 2 and 3). Urgent consultation with a Pediatric HIV specialist is indicated for all cases.
    f. In the situation where cART is recommended for the infant zidovudine, lamivudine and nevirapine is the preferred regimen. When there is documented non-nucleoside reverse transcriptase inhibitor (nevirapine) resistance in the mother, raltegravir-based infant cART is the preferred treatment option (instead of nevirapine-based cART). Raltegravir granules for oral suspension are currently only available through Health Canada's Special Access Program.

4. Women with known HIV infection, irrespective of antiretroviral therapy, whose viral load during pregnancy has not been measured or is not known
    a. Involvement of an adult and a pediatric HIV specialist as well as an Obstetrician with expertise in HIV is recommended
    b. Draw blood for viral load measurement (depending on stage of pregnancy this may need to be done STAT)
    c. Combination ART should be initiated in the woman if not already done; integrase strand transfer inhibitor (INSTI)-based cART should be considered when treatment is started in the third trimester.
    d. Intravenous Zidovudine during labor until delivery
    e. Elective Cesarean section should be strongly considered if not in labor
        - If viral load greater than 1000 copies/mL, elective Cesarean section should be recommended unless contraindicated for maternal health reasons (see item A3d above). Consultation with an Obstetrician with expertise in HIV management is indicated for all cases.

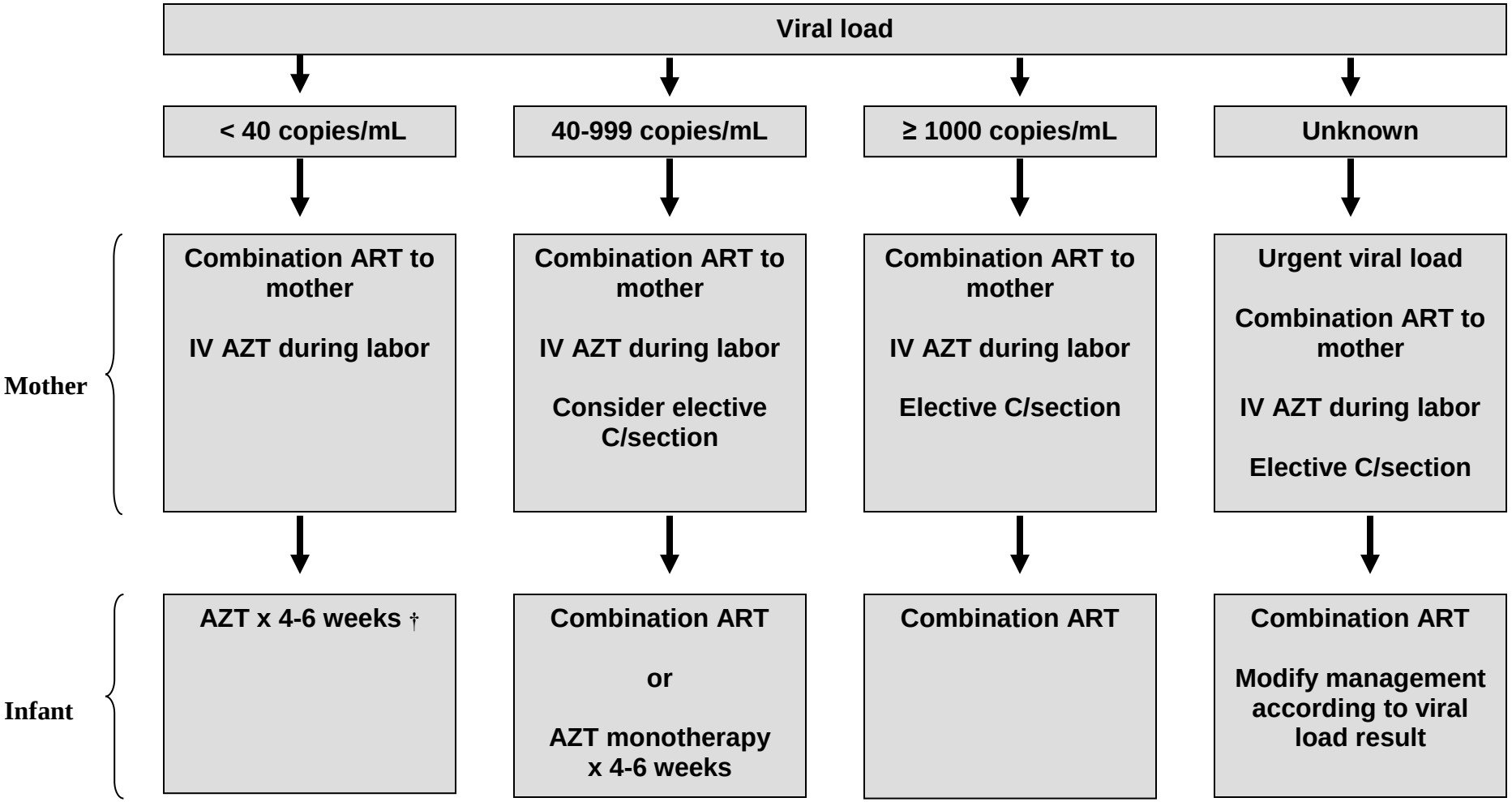
- If viral load is detectable, but less than 1000 copies/mL elective Cesarean section should still be considered and counseling provided in this regard (see item A2c above).

f. Infant antiretroviral therapy will depend on maternal viral load test results. Consultation with a pediatric HIV specialist is indicated for all cases.
   - If maternal viral load is available at the time of delivery, manage as for scenarios 1 through 3 above.
   - If maternal viral load is not available in the immediate post-partum period - cART for the infant should be initiated. Subsequent modification of ART should be based on maternal viral load results.
     - If the maternal viral load is undetectable step-down to Zidovudine monotherapy
     - If maternal viral load is ≥ 40 copies/mL, cART should be continued

5. Women with known HIV infection who are not receiving cART and who **have a documented undetectable viral load**.
   a. Involvement of an adult and a pediatric HIV experts as well as an Obstetrician with expertise in HIV is recommended
   b. Initiation of cART should be considered in consultation with an adult HIV expert
   c. Intravenous Zidovudine during labor is indicated
   d. Elective Cesarean section is not routinely recommended
   e. Zidovudine prophylaxis for infant is recommended

6. Women with known HIV infection who present in labor, did not receive cART prior to the onset of labor and who have a viral load greater than 40 copies/mL or unknown viral load
   a. Consultation with adult and pediatric HIV specialists as well as an Obstetrician with expertise in HIV management is recommended.
   b. Intravenous Zidovudine during labor until delivery
   c. Emergency Cesarean section should be considered
   d. Combination ART is indicated for the infant (see Tables 2 and 3); consultation with a pediatric HIV specialist is indicated for all cases.

Management summary for mother-infant pairs with documented maternal HIV infection with initiation of management late in gestation prior to onset of labor §



§ After delivery, in the immediate post-partum period, the need for continuing combination antiretroviral therapy in women for their own health should be reassessed.

† For full-term infants zidovudine can be stopped at 4 weeks if the mother had received cART during pregnancy, had sustained viral suppression and there were no concerns related to maternal adherence (see item A1c for details)

B. Women with unknown/undocumented HIV status who present in labor (see Table 4 for specific suggested interventions)

It is recognized that the degree of risk of HIV infection among women with unknown/undocumented HIV status is variable. **Consultation with adult and pediatric HIV specialists as well as an Obstetrician with expertise in HIV is indicated for all such cases.**

1. Women with unknown HIV status presenting in labor who have known risk factors for HIV infection (e.g. recent arrival in Canada as immigrants or refugees from countries with high HIV prevalence rates; history of commercial sex work or multiple sexual partners without condoms; history or suspicion of injection drug use):
    a. Consultation with adult and pediatric HIV experts as well as an Obstetrician with expertise in HIV is indicated for all such cases
    b. STAT HIV serology is warranted to guide management
        - Pre-test counseling with informed consent must precede HIV testing
        - Other molecular HIV testing strategies may be considered in specific circumstances in consultation with an HIV expert (e.g. HIV-1 viral load or HIV-1 PCR testing may be considered on an individual basis to detect very recent HIV infection that could be missed by serology [window period])
        - If HIV-1 molecular testing is recommended for the mother, the following should be written on the requisition. "High risk mother with negative HIV serology. Please perform HIV-1 viral load/PCR."
    c. Intrapartum intravenous Zidovudine should be recommended if STAT HIV serologic testing is positive
    d. Emergency Cesarean section may be considered depending on the duration of membrane rupture if STAT HIV serologic testing is positive
    e. Combination ART for the infant is warranted if STAT HIV serologic testing is positive (Tables 2 and 4). Combination ART consisting of zidovudine, lamivudine and nevirapine at treatment doses is the preferred treatment option for such situations (Tables 2 and 4). When there is documented non-nucleoside reverse transcriptase inhibitor (nevirapine) resistance in the mother, raltegravir-based infant cART is the preferred treatment option (instead of nevirapine-based cART). Raltegravir granules for oral suspension are currently only available through Health Canada's Special Access Program.
    f. If STAT HIV serology is negative, the decision to initiate treatment for the infant should be based on an assessment of the risk of maternal HIV infection late in gestation. The possibility of the mother being in the "window period" needs to be considered.
        - Combination ART of the infant may be considered if the mother is thought to be at **substantial risk of HIV acquisition late in gestation (e.g. frequent ongoing intravenous drug use, commercial sex work, or other known HIV exposure during last 2 weeks of gestation)** (see Tables 2 and 4).

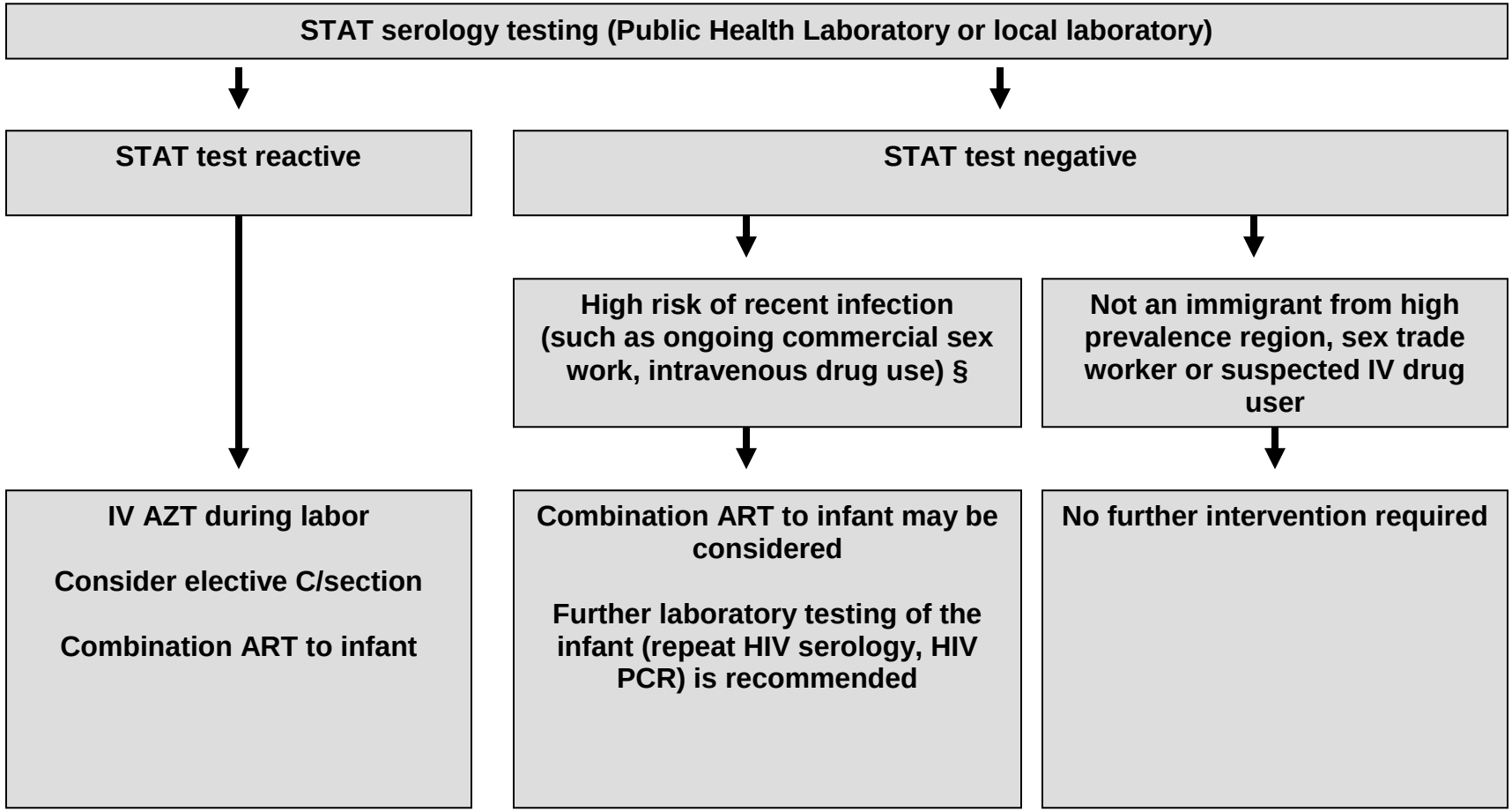
- If the infant is started on treatment before availability of test results, the need for continued treatment should be reassessed once test results become available. If both HIV serology and molecular testing on the mother from the time of delivery are negative, infant treatment can be stopped.

2. Women presenting in labor with unknown HIV status who are not recent immigrants or refugees from countries with high HIV prevalence rates, commercial sex workers or known or suspected to be injecting street drugs
    a. STAT HIV serology is warranted to guide management
        - HIV testing should be offered to all such women
        - Pre-test counseling with informed consent must precede HIV testing
    b. In general, antiretroviral therapy should not be given in these circumstances unless STAT HIV serologic testing is positive
    c. If the STAT HIV serologic test is positive consultation with adult and pediatric HIV experts as well as an Obstetrician with expertise in HIV management is essential; management should be as described in scenario B1c through B1f

3. Women of unknown HIV status who refused HIV testing during pregnancy, but agree to STAT testing of themselves during labor or of the baby in the immediate post-partum period
    a. Management of the mother and infant should be directed by the clinical history and as described in scenario B1 and B2 above

4. Women of unknown HIV status who refuse HIV testing of themselves and their newborn infant
    a. Consultation with adult and pediatric HIV specialists is indicated for **ALL** such cases.
    b. STAT HIV testing of newborn infants considered to be at high risk of HIV is warranted, but requires consent of the legal guardian. It should be recognized that testing of the infant in this circumstance is equivalent to testing the mother.
    c. Combination ART for newborn infants deemed to be at high risk should be considered pending test results (see item B1 above and Tables 2 and 4)
    d. Refusal of infant HIV testing in and of itself is not grounds to involve the Children's Aid Society (CAS). However, notification of CAS may be considered if in the opinion of the treating physician and consulting adult and pediatric HIV experts the risk of HIV is substantial, intervention is warranted and the parents are refusing testing and treatment.

Management summary for mother-infant pairs with unknown/undocumented maternal HIV status in labor (Management of the Infant must involve consultation with a pediatric HIV expert)



§ **The rationale for considering prophylactic ART in this scenario is that a recently infected mother may have not sero-converted yet (see pages 14-15 for details)**

Table 1: Intrapartum antiretroviral medications for mothers §

Medication	Dose
Zidovudine	Initial intravenous infusion of 2 mg/kg over 1 hour followed by a continuous infusion of 1 mg/kg/hour until delivery

§ Many other antiretroviral medications are used during pregnancy; the standard oral dosing apply; combination antiretroviral therapy initiated prior to or during the pregnancy should be continued during labor

Table 2: Prophylactic antiretroviral medication dosing in newborn infants ¶ £

Medication	Gestation	Dose
Zidovudine	≥ 35 weeks gestation at birth	Birth –6 weeks of age: 4 mg/kg/dose PO q12h; IV dosing should be 75% of oral dose with same dosing interval
	≥ 30 to < 35 weeks gestational age at birth	Birth – 2 weeks of age: 2 mg/kg/dose PO q12h; 2 – 6 weeks of age: 3 mg/kg/dose PO q12h; IV dosing should be 75% of oral dose with same dosing interval
	< 30 weeks gestation at birth	Birth – 4 weeks: of age 2 mg/kg/dose PO q12h; 4 – 6 weeks of age: 3 mg/kg/dose PO q12h IV dosing should be 75% of oral dose with same dosing interval
Lamivudine	≥ 32 weeks gestational age at birth	< 4 weeks of age: 2 mg/kg/dose PO given q12h ≥ 4 weeks of age: 4 mg/kg/dose (max 150 mg/dose) PO given q12h ₴
Nevirapine §	≥ 34 weeks gestation at birth	150 mg/m^2/dose once daily PO for first 2 weeks, then 150 mg/m^2/dose q12h PO for 2 weeks § * Three dose regimen: 8 mg/dose (birth weight 1.5-2.0 kg) or 12 mg/ dose (birth weight > 2 kg) administered within 48 hours of birth and repeated 48 hours after first dose and 96 hours after second dose
	< 34 weeks gestation at birth	100 mg/m^2/dose once daily PO for first 2 weeks, then 100 mg/m^2/dose q12h PO for 2 weeks § * Three dose regimen: 8 mg/dose (birth weight 1.5-2.0 kg) or 12 mg/ dose (birth weight > 2 kg) administered within 48 hours of birth and repeated 48 hours after first dose and 96 hours after second dose
Raltegravir ¥	≥ 37 weeks	1.5 mg/kg/dose PO once daily from birth to day 7 followed by 3.0 mg/kg/dose PO BID until 4 weeks of age followed by 6 mg/kg/dose PO BID to age 6 weeks ‡
	< 37 weeks	Start at 1.5 mg/kg/dose PO on the day of birth and every 1-3 days afterwards (depending on gestational age/birth weight), and adjust in accordance with therapeutic drug monitoring results ₸
Lopinavir/ritonavir (Kaletra®) †	Term †	300 mg/ m^2/dose of lopinavir (which includes 75 mg/m^2/dose of ritonavir) PO q12h Dosing guidelines based on published data for term infants 14 days of age or older

Abbreviations: PO = per os (oral); IV = intravenously; q6h = every 6 hours; q8h = every 8 hours; q12h = every 12 hours

¶ Dosing provided only for antiretroviral agents listed in the current protocol

£ Treatment should be initiated as soon as possible and preferably within 6-12 hours of birth

₴ Some centers only increase the lamivudine dose at 4 weeks for HIV positive infants

§ Nevirapine is available through Health Canada Special Access Program. Trough nevirapine levels in serum should be checked 7 days and 14 days after starting nevirapine therapy and the nevirapine dose adjusted as required in consultation with a pharmacist familiar with antiretroviral medications.

* An investigational treatment dose for nevirapine is currently suggested in the U.S. Department of Health and Human Services guidelines: 6 mg/kg/dose administered twice daily for term neonates born at ≥ 37 weeks gestation, and 4 mg/kg/dose twice daily x 1 week then 6 mg/kg/dose twice daily for neonates born at 34-36 weeks gestation.

¥ Neonatal dosing is currently experimental. Only available through Health Canada Special Access Program.

‡ Dosing for term infants derived from IMPACT P1110 (no data for preterm neonates). Weight band-based dosing for infants 4 weeks of age or older: 3.0 - <4.0 kg: 20 mg/dose PO BID; 4.0 - <6.0 kg: 30 mg/dose PO BID. Routine therapeutic drug monitoring recommended; initially this should be done weekly in consultation with a clinician and pharmacist familiar with antiretroviral medications.

₸ Gestational age and birth weight need to be taken into account in deciding on the dosing interval as there are no clinical trial data at present. For extremely premature infants a tentative dosing interval of 72 hours is suggested with therapeutic drug monitoring at 3-5 day intervals; for less premature infant a dosing interval of 1-2 days may be reasonable. Consultation with a clinician and pharmacist familiar with antiretroviral medications is recommended for all cases.

† Lopinavir/ritonavir should only be used in neonates in extraordinary circumstances after consultation with a pediatric HIV expert; it is currently recommended that Kaletra® not be used in infants until a postmenstrual age of 42 weeks and a postnatal age of at least 14 days. Reported toxicities in premature infants, from the drug itself and/or from the inactive ingredients in the oral solution (propylene glycol, ethanol), include transient symptomatic adrenal insufficiency; life-threatening bradyarrhythmias and cardiac dysfunction; and lactic acidosis, acute renal failure, central nervous system (CNS) depression, and respiratory depression.

Table 3: Management of mother-infant pairs when mothers HIV status in known prior to onset of labor and infant is ≥35 weeks gestational age at birth § £

Maternal scenario	Intrapartum	Infant § £ † ‖
Known HIV positive on cART with documented recent viral load <40 copies/mL	Zidovudine 2 mg/kg IV loading dose over 1 hour beginning as soon as possible after the onset of labor followed by 1 mg/kg/hour infusion until delivery; continue other antiretroviral medications during labor and delivery	Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth for a total of 4-6 weeks. For full-term infants the zidovudine can be stopped at 4 weeks if the mother had received cART during pregnancy, had sustained viral suppression and there were no concerns related to maternal adherence. In other circumstances a 6 week course is recommended, although in selected cases it may be reasonable to give only 4 weeks (e.g. significant anemia attributable to zidovudine)
Known HIV positive on cART with documented recent viral load 40-999 copies/mL	Zidovudine 2 mg/kg IV loading dose over 1 hour beginning as soon a possible after the onset of labor followed by 1 mg/kg/hour infusion until delivery; continue other antiretroviral medications during labor and delivery Elective Cesarean section prior to onset of labor should be considered; if already in labor consider Cesarean section if membranes ruptured for more than 4 hours	**Option 1:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Lamivudine 2 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth until 4 weeks of age, then 4 mg/kg/dose q12h PO for an additional 2 weeks *PLUS* Nevirapine 150 mg/m^2/dose PO once daily for 2 weeks beginning within 6 to 12 hours of birth then 150 mg/m^2/dose q12h PO for 2 weeks (total of 4 weeks) * ¥ **Option 2:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Nevirapine 8 mg/dose if birth weight 1.5-2.0 kg or 12 mg/dose if birth weight > 2 kg administered within 48 hours of birth and repeated 48 hours after first dose and 96 hours after second dose **Option 3:** ‡ Zidovudine 4mg/kg/dose q12h PO IV beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks
Known HIV positive on cART with inadequately controlled	Zidovudine 2 mg/kg IV loading dose over 1 hour beginning as soon a possible after the onset of labor	**Option 1:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth.

HIV (viral load ≥1000 copies/mL)	followed by 1 mg/kg/hour infusion until delivery; continue other antiretroviral medications during labor and delivery Elective Cesarean section prior to onset of labor; if already in labor consider Cesarean section if membranes ruptured for more than 4 hours	Continue oral Zidovudine for a total of 6 weeks *PLUS* Lamivudine 2 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth until 4 weeks of age, then 4 mg/kg/dose q12h PO for an additional 2 weeks *PLUS* Nevirapine 150 mg/m^2/dose PO once daily for 2 weeks beginning within 6 to 12 hours of birth then 150 mg/m^2/dose q12h PO for 2 weeks (total of 4 weeks) * ¥ **Option 2:** Zidovudine 4 mg/kg/dose q12h PO or 3 mg/kg/dose q12h IV beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Nevirapine 8 mg/dose if birth weight 1.5-2.0 kg or 12 mg/ dose if birth weight > 2 kg administered within 48 hours of birth and repeated 48 hours after first dose and 96 hours after second dose
Known HIV positive on cART, but viral load not done or is not known	Stat viral load Zidovudine 2 mg/kg IV loading dose over 1 hour beginning as soon a possible after the onset of labor followed by 1 mg/kg/hour infusion until delivery; continue other antiretroviral medications during labor and delivery Elective C/section should be considered depending on viral load result	**If viral load available at time of delivery, manage as for above scenarios.** **If viral load not available at time of delivery and there are concerns regarding maternal adherence, consider combination therapy (once viral load results become available, modify treatment according to above scenarios):** **Option 1:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Lamivudine 2 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth until 4 weeks of age, then 4 mg/kg/dose q12h PO for an additional 2 weeks *PLUS* Nevirapine 150 mg/m^2/dose PO once daily for 2 weeks beginning within 6 to 12 hours of birth then 150 mg/m^2/dose q12h PO for 2 weeks (total of 4 weeks) * ¥ **Option 2:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Nevirapine 8 mg/dose if birth weight 1.5-2.0 kg or 12 mg/ dose if birth weight > 2 kg administered within 48 hours of birth and repeated 48 hours after first dose and 96 hours after second dose

Known HIV positive, no ART and viral load < 40 copies/mL	Zidovudine 2 mg/kg IV loading dose over 1 hour followed by 1 mg/kg/hour infusion until delivery; continue other antiretroviral medications during labor and delivery Elective C/section is not routinely recommended	Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks
Known HIV positive, no ART prior to onset of labor (and presenting in labor), viral load unknown or known to be elevated (≥ 40 copies/mL)	Zidovudine 2 mg/kg IV loading dose over 1 hour followed by 1 mg/kg/hour infusion until delivery; continue other antiretroviral medications during labor and delivery Emergency Cesarean section should be considered	**Option 1:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Lamivudine 2 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth until 4 weeks of age, then 4 mg/kg/dose q12h PO for an additional 2 weeks *PLUS* Nevirapine 150 mg/m^2/dose PO once daily for 2 weeks beginning within 6 to 12 hours of birth then 150 mg/m^2/dose q12h PO for 2 weeks (total of 4 weeks) * ¥ **Option 2:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Nevirapine 8 mg/dose if birth weight 1.5-2.0 kg or 12 mg/dose if birth weight > 2 kg administered within 48 hours of birth and repeated 48 hours after first dose and 96 hours after second dose

Abbreviations: PO = per os (orally); IV = intravenously; q6h = every 6 hours; q12h = every 12 hours

§ Zidovudine dosing is as per recommendations for infants ≥ 35 weeks gestation at the time of birth; for infants with a gestational age < 35 weeks at the time of birth please refer to table 2; IV dose should be 75% of recommended oral dose at same

£ Treatment should be initiated as soon as possible and preferably within 6-12 hours of birth

† Consultation with a pediatric HIV specialist is recommended for all children in whom combination antiretroviral therapy is being considered

‖ Raltegravir should be used in place of nevirapine in presence of documented nevirapine resistance in the mother. If neither nevirapine or raltegravir is an option (e.g. resistance), lopinavir/ritonavir may be considered; however, due to potentially serious toxicities that can be fatal, lopinavir/ritonavir should only be considered in extraordinary circumstances – consultation with a pediatric HIV expert is essential.

‡ Zidovudine monotherapy is reasonable in the setting of detectable, but very low viral load, particularly if an elective Cesarean section is performed

* An investigational treatment dose for nevirapine of 6 mg/kg/dose administered twice daily for term neonates < 1 month of age has been suggested in the U.S. Department of Health and Human Services guidelines. This dose is under evaluation at present.

¥ Raltegravir should be used in place of nevirapine in presence of documented nevirapine resistance in the mother (see Table 2 for dosing)

Table 4: Management of mother-infant pairs when mothers HIV status in not known at the time of presentation in labor and the infant is ≥ 35 weeks gestational age at birth ¶ § £

Maternal scenario	Intrapartum	Infant § £ † ‖
STAT HIV serology positive	Consult Infectious Diseases expert and Obstetrician with expertise in HIV management Send STAT maternal viral load Zidovudine 2 mg/kg IV loading dose over 1 hour followed by 1 mg/kg/hour infusion until delivery; continue other antiretroviral medications during labor and delivery Elective C/section should be considered	**Option 1:** Zidovudine 4 mg/kg/dose q12h PO within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Lamivudine 2 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth until 4 weeks of age, then 4 mg/kg/dose q12h PO for an additional 2 weeks ***PLUS*** Nevirapine 150 mg/m^2/dose PO once daily for 2 weeks beginning within 6 to 12 hours of birth then 150 mg/m^2/dose q12h PO for 2 weeks (total of 4 weeks) * **Option 2:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Nevirapine 8 mg/ dose if birth weight 1.5-2.0 kg or 12 mg/ dose if birth weight > 2 kg administered within 48 hours of birth and repeated 48 hours after first dose and 96 hours after second dose
STAT HIV serology negative, but known high risk behavior during the preceding 2 weeks	Consult Infectious Diseases expert and Obstetrician with expertise in HIV management Consider HIV-1 maternal viral load testing if clinical scenario suggestive of possible recent HIV exposure/infection In general no specific preventative interventions are warranted; however such intervention may be considered in unusual scenarios (see text for details)	**The decision to prescribe ART should be individualized based on degree of perceived risk – in the majority of such cases the risk of adverse effects from the medications may outweigh their potential benefit; if given, the recommended treatment options consist of:** **Option 1:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Lamivudine 2 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth until 4 weeks of age, then 4 mg/kg/dose q12h PO for an additional 2 weeks *PLUS* Nevirapine 150 mg/m^2/dose PO once daily for 2 weeks beginning within 6 to 12 hours of birth then 150 mg/m^2/dose q12h PO for 2 weeks (total of 4 weeks) *

		Option 2: Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Nevirapine 8 mg/dose if birth weight 1.5-2.0 kg or 12 mg/dose if birth weight > 2 kg administered within 48 hours of birth and repeated 48 hours after first dose and 96 hours after second dose **If started, ART should be discontinued if maternal HIV-1 viral load is negative**
STAT HIV test negative, no known high risk behavior during the preceding 2 weeks	No intervention indicated	No treatment indicated
Mother refuses testing and treatment of herself	Urgent Pediatric Infectious Diseases consultation Consider involvement of Children's Aid Society (see item B4, page 14)	**The decision to prescribe ART should be individualized and should preferably be based on STAT testing of the infant– in the majority of such cases the risk of adverse effects from the medications may outweigh their potential benefit; if given, the recommended treatment options consist of:** **Option 1:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Lamivudine 2 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth until 4 weeks of age, then 4 mg/kg/dose q12h PO for an additional 2 weeks *PLUS* Nevirapine 150 mg/m^2/dose PO once daily for 2 weeks beginning within 6 to 12 hours of birth then 150 mg/m^2/dose q12h PO for 2 weeks (total of 4 weeks) * **Option 2:** Zidovudine 4 mg/kg/dose q12h PO beginning within 6 to 12 hours of birth. Continue oral Zidovudine for a total of 6 weeks *PLUS* Nevirapine 8 mg/dose if birth weight 1.5-2.0 kg or 12 mg/dose if birth weight > 2 kg administered within 48 hours of birth and repeated 48 hours after first dose and 96 hours after second dose **If ART started prior to availability of STAT test results, ART should be discontinued if test results (HIV serology ± HIV-1 viral load) are negative**

Abbreviations: ART = antiretroviral therapy; PO = per os (orally); IV = intravenously; q6h = every 6 hours; q12h = every 12 hours

¶ It is assumed that women in this category would not have been treated with cART during pregnancy

§ Zidovudine dosing is as per recommendations for infants ≥ 35 weeks gestation at the time of birth; for infants with a gestational age < 35 weeks at the time of birth please refer to table 2; IV dose should be 75% of recommended oral dose at same interval

£ Treatment should be initiated as soon as possible and preferably within 6-12 hours of birth

† Consultation with a pediatric HIV specialist is recommended for all children in whom combination antiretroviral therapy is being considered

‖ Raltegravir should be used in place of nevirapine in presence of documented nevirapine resistance in the mother. If neither nevirapine or raltegravir is an option (e.g. resistance), lopinavir/ritonavir may be considered; however, due to potentially serious toxicities that can be fatal, lopinavir/ritonavir should only be considered in extraordinary circumstances – consultation with a pediatric HIV expert is essential.

* An investigational treatment dose for nevirapine of 6 mg/kg/dose administered twice daily for term neonates < 1 month of age has been suggested in the U.S. Department of Health and Human Services guidelines. This dose is under evaluation at present.

Appendix 1: Ontario HIV Outpatient Clinic Coordinator / Director Network (OCN) - Contact Information

(*) – clinic coordinators / managers / main contacts

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Appendix 2: HIV 1 viral load testing information

***HIV* Viral Load**

TEST INFORMATION SHEET

SPECIMEN REQUIREMENTS
Specimen Type: Plasma or whole blood
Container/Kit: Blood collected in EDTA or PPT tubes. Collect 1x10 mL tube or 2 x 7.0 mL tubes *Whole blood submitted in EDTA or PPT tubes must be received at your local PHO Public Health Laboratory within 6 hours of collection of the blood (PPT tubes that have been centrifuged within 6.0 hours of collection must be received at PHO laboratories within 24 hours of collection-before 2:00 p.m. Monday - Friday. Alternately, centrifuge tube and transfer plasma to provided Viral Load polypropylene transport vial within 6 hours of collection and freeze.
Collection information: To order Collection Kits or other PHOL Supplies complete the Requisition for Containers and Supplies. The form should be faxed to Public Health Ontario Laboratory, Toronto at 416-235-5753 or your local PHOL.
Minimum volume required: 2.5 mL frozen plasma or 2 EDTA or PPT blood tubes
Requisition: Complete the HIV Viral Load Form.
Limitation: None
SPECIMEN HANDLING
Preparation prior to transport: Place specimen in a biohazard bag and seal. Vials should be stored frozen following collection. Frozen specimens should be shipped to the nearest PHO Laboratory within 2-3 days to prevent delay in testing. Ship frozen on dry ice or ice packs.
Special Instructions: None
TEST INFORMATION:
Specimens for quantitative *HIV* Viral Load are tested by RT PCR using the Abbott *HIV* 1 Viral Load Assay. The Abbott Real Time *HIV* 1 test uses the m2000 automated system. It is an in vitro reverse transcription - polymerase chain reaction assay for the quantitation of *HIV* 1 in human plasma.
ADDITIONAL INFORMATION:
Viral load testing is only available to patients known to be *HIV* positive. Ensure that the Viral Load Requisition is completed in full. The following information is often missing on the Viral Load Requisition: HIN/OHIP number, CD4 and current viral therapy and specimen collection information at the bottom of the form. Specimens will not be processed if the information is incomplete.
TESTING FREQUENCY AND TURNAROUND TIME (TAT):
TAT is up to 6 days.
REPORTING:
Results are reported to the ordering physician or health care provider as indicated on the requisition.

Public Health Ontario
PARTNERS FOR HEALTH

Santé publique Ontario
PARTENAIRES POUR LA SANTÉ

Public Health Laboratory
Laboratoire de santé publique

Labstract – September 2010

Public Health Laboratories Implement New Viral Load Test for HIV1

To health care providers:

Effective August 16, 2010, the Ontario Agency for Health Protection and Promotion (OAHPP) public health laboratories (PHL) began to transition to a new human immunodeficiency virus (HIV)-1 Viral Load assay. The first site to convert to the new system will be PHL, Toronto. All four Ontario HIV1 Viral Load testing sites are expected to be converted by the end of October, 2010.

The Abbott RealTi*m*e HIV1 test which uses the m2000 automated system will replace the current Siemens bDNA test system. In the comparison of the two assays, the viral loads correlate well with 99 per cent of values within 1 log (10) copies/ml between tests.

This new assay is an in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantitation of HIV-1 in human plasma from HIV-1 infected individuals with results in the range of 40 to 10,000,000 copies/mL. This assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in plasma HIV-1 RNA levels.

Until the transition to the new assay is complete, HIV-1 viral load samples may be tested by either one of these two assays.

How to interpret what assay was used?

- If the HIV test indicates "Abbott HIV 1 Viral Load (RT PCR)" then the specimen has been tested using the new Abbott test system.
- If the HIV test indicates "Versant HIV1 bDNA 3.0" then it was tested using the Siemens test system.

For further information:

- Contact the PHOL Customer Service Centre at 416-235-6556 or toll free at 1-877-604-4567, or via email at customerservicecentre@oahpp.ca
- For the PHOL Specimen Collection Guide and previous Labstracts, refer to http://www.oahpp.ca/services/public-health-laboratories.html
- To subscribe to labstracts, please e-mail labstracts@oahpp.ca
- Public Health Agency of Canada website: www.phac-aspc.gc.ca

Ontario
Agency for Health Protection and Promotion
Agence de protection et de promotion de la santé

Labstract – December 2015

HIV-1 PCR - New version of the Cobas Ampliprep/Cobas Taqman Qualitative Test

To Health Care Providers

The Public Health Ontario Laboratories (PHOL) has replaced its current Cobas Ampliprep/ Cobas Taqman HIV- 1 Qualitative Test, version 1.0 assay with the version 2.0 assay. The version 1.0 assay will no longer be supported by the manufacturer, Roche Molecular Diagnostics.

The HIV PCR qualitative test detects the presence of virus in blood samples and is primarily used for the diagnosis of HIV infection in babies born to HIV positive mothers. Testing only for HIV antibody in such patients is inadequate for diagnosis because of the presence of maternal HIV antibody. In testing babies born to HIV positive mothers it is recommended that a first HIV PCR test be performed at or near the time of birth followed by 2 subsequent PCRs at least 1 month apart. The 3rd PCR should be done between 2 and 6 months of age, depending on the circumstances. This should then be followed by an antibody test at 18 months of age for confirmation.

The HIV PCR test may be used in other clinical situations such as needle stick injuries, sexual assault and other special circumstances but cannot be relied upon as a diagnostic test in these settings. Submitters should consult with one of the PHO medical/clinical microbiologists for more specific advice in these situations, and notification and approval is required prior to PCR testing.

Please note that serology will also be performed on all plasma and whole blood samples submitted for HIV PCR.

WHAT HAS CHANGED:

Version 2.0 of Cobas Ampliprep/ Cobas Taqman HIV-1 Qualitative Test has the following changes compared to the now obsolete Version 1.0 (Please see Tables 1, 2 & 3 below for full details):

- Detects dual targets (HIV-1 Gag gene & HIV-1 LTR region) to ensure more reliable results
- Has a lower limit of detection (LLD)
- Has revised minimum specimen volume and storage requirements
- Changes in reporting of results

Table 1. Limit of detection for Cobas Ampliprep/ Cobas Taqman HIV-1 Qualitative Test

Specimen Type	Version 1.0	Version 2.0
Plasma	~500 copies/mL	16.5 copies /mL
Dried Blood Spots (DBS)	~1100 copies/mL	221.8 copies /mL
Whole Blood	~700 copies/mL	20 copies/mL *

*Based on in-house testing

Table 2. Sample submission details for Cobas Ampliprep/ Cobas Taqman HIV-1 Qualitative Test Version 2.0 including appropriate specimens, specimen volume, specimen storage

Appropriate specimen types	Minimum specimen volume required for testing	Specimen storage requirements	Notes
Whole blood collected in EDTA	Minimum 2000 uL (or 2mL) for both PCR and antibody testing A minimum of 400 uL of whole blood is required for the PCR testing alone. If less than 2000 uL of whole blood is submitted PCR will be prioritized	Whole blood may be stored for up to 12 hours at room temperature or for an additional 72 hours at 2 to 8°C prior to separation of plasma or preparation of cell pellets. Do not freeze whole blood.	Blood samples collected in heparin-containing tubes will be rejected.
Plasma	Minimum 3000 uL (or 3.0 mL) for both PCR and antibody testing A minimum of 1100 uL of plasma is required for the PCR testing alone. If less than 3000 uL is submitted, testing by PCR will be prioritized.	Plasma can be stored at 25 to 30°C for one day, 2 to 8°C for up to 5 days and frozen at -20°C to -80°C for 6 weeks.	Note this is equivalent to approximately 5000 uL (or 5.0 mL) of whole blood.
Dried blood spots (DBS)	Minimum 4 DBS per patient Please note that antibody testing will not be performed on DBS.	DBS can be stored at ambient temperature for up to three months and shipped to the PHL in individual re-sealable plastic bags with a desiccant sachet in each bag.	For DBS preparation, please refer to LAB-SD-086 HIV-1 Qual Test using Dried Blood Spots (DBS) by Cobas Ampliprep/Cobas Taqman http://www.publichealthontario.ca/Labs

Table 3. Results Reporting and Interpretation Cobas Ampliprep/ Cobas Taqman HIV-1 Qualitative Test Version 2.0

Reported Test Name	Result	Interpretation
HIV 1 PCR	Detected	HIV 1 Detected
	Not Detected	HIV 1 Not Detected
	Indeterminate*	Indeterminate HIV 1 result

*Occasionally, samples may contain inhibitors to the PCR reaction resulting in an uninterpretable test result. Other factors may also affect the ability of the test to yield a valid result (e.g. extremely high viral load). These will be reported as "Indeterminate" and a repeat sample will be requested.

For further information:

- Contact the PHOL Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at CustomerServiceCentre@oahpp.ca
- For PHOL specimen collection information and previous Labstracts, refer to http://www.publichealthontario.ca/Labs
- The current version of the PHOL General Test Requisition and other forms are available at http://www.publichealthontario.ca/Requisitions
- To subscribe to future Labstracts, email labstracts@oahpp.ca
- To register for Autofax and receive laboratory reports by fax directly from our laboratory information system as soon as they are released, contact the PHOL Customer Service Centre.

References:

1. Sergio Carmona et al. Improved Sensitivity of a Dual-Target HIV-1 Qualitative Test for Plasma and Dried Blood Spots, National Health laboratory Service, Johannesburg, Republic of South Africa.
2. Product Insert – COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0. Roche Molecular Systems, Inc. March 2015

Labstract - May 2016

HIV patient information sheet

To Healthcare Providers:

Effective June 1, 2016, the Public Health Ontario Laboratory (PHOL) will attach the enclosed information sheet to reports of positive tests for human immunodeficiency virus (HIV) types 1 and 2.

The information sheet was prepared by the Canadian AIDS Treatment Information Exchange (CATIE). It will provide HIV-positive persons with important information to understand and manage their HIV diagnosis, including:

- how to access a health care provider knowledgeable about HIV
- resources and supports
- the role of public health in HIV reporting and contact notification
- how to prevent transmission to others

For more information, visit www.catie.ca.

We are attaching this information sheet to all new positive HIV test results to help you support clients with important links to care and treatment, at a critical time when they will benefit from assurance and clear, easy to understand materials.

Please share this information with your clients when you inform them of the positive test result, to ensure they have access to important resources.

HIV patient information sheet (continued)

For further information:

- Contact the PHOL Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at CustomerServiceCentre@oahpp.ca
- For PHOL specimen collection information and previous Labstracts, refer to http://www.publichealthontario.ca/Labs
- The CATIE information sheet is also posted at www.catie.ca/sites/default/files/newly%20diagnosed%20fax%20EN%202016%2001%2019a.pdf
- The current version of the PHOL General Test Requisition and other forms are available at http://www.publichealthontario.ca/Requisitions
- To subscribe to future Labstracts, email labstracts@oahpp.ca
- To register for Autofax and receive laboratory reports by fax directly from our laboratory information system as soon as they are released, contact the PHOL Customer Service Centre.

Appendix 3: Abbreviations:

ART	Antiretroviral therapy
cART	Combination antiretroviral therapy
HIV	Human immunodeficiency virus
PCR	Polymerase chain reaction
PHOL	Public Health Ontario Laboratory