Women's Health Program Guidelines and Protocols

Reducing the Rate of Perinatal HIV Transmission for Mothers and Babies

TABLE OF CONTENTS

Women's Health Program Guidelines and Protocols

Reducing the Rate of Perinatal HIV Transmission for Mothers and Babies

This document is an Edmonton Zone document for patients followed by the Northern Alberta Program, which covers a geographical area from north of Red Deer to the very northern part of the province of Alberta. This guideline is a joint production of the Northern Alberta HIV Program, Division of Infectious Diseases (Adult and Pediatrics), Department of Medicine, University of Alberta, Edmonton Zone Women's Health Program, Edmonton Zone Pharmacy Services, Edmonton Zone Division of Child Health and Newborn Medicine, Edmonton Zone Primary Care, Chronic Disease Management and Public Health.

At Covenant Health Group facilities, references to contraceptive practices, assisted fertilization and counselling options regarding the continuation of pregnancies must be balanced with the moral considerations and prohibitions presented in the Health Ethics Guide, the foundational ethical framework used in Catholic healthcare institutions, including Covenant. The principle of legitimate cooperation may apply in some instances. An ethics consult is recommended to help interpret specific cases where this applies.

AHS Knowledge Resource Service, HIV/AIDS page
http://krs.libguides.com/content.php?pid=452758&sid=4589197

Bugs & Drugs, Links
http://www.bugsanddrugs.ca/documents/HIV_Protocol.pdf

These guidelines represent the current state of knowledge and will be updated as new information becomes available.

Introduction

The number of HIV-infected women overall and HIV-infected pregnant women in particular, is increasing in northern Alberta. The average risk of HIV transmission to the baby of an infected mother is approximately 25% in the absence of any intervention. Appropriate treatment with antiretroviral medication (and in selected circumstances, scheduled caesarean section) can reduce the risk of maternal-fetal HIV transmission dramatically. The rate of transmission appears to be less than 1-2% in women whose HIV disease is well controlled during pregnancy, and is markedly reduced even when treatment is started late in pregnancy or during delivery.

Neonatal HIV infection is therefore a largely preventable disease. Identifying pregnant women who are HIV-infected and ensuring they receive appropriate antiretroviral therapy are important prevention opportunities.

Pre-Conception Care

More women with HIV or with partners with HIV are considering pregnancy because of the therapeutic advances in HIV care as well as dramatic reductions in perinatal transmission. Women wishing to pursue pregnancy should be referred for preconception care to reduce the risks of perinatal transmission and transmission to uninfected partners. Preconception care and counseling should address the following:

1. Discuss the woman's childbearing plans and desires to reduce the risk of unintended pregnancy and the use of medication with potential reproductive toxicity.
2. Assess for the use of contraceptive methods to minimize the risk of viral transmission and unintended pregnancy. Allow time to optimize maternal health status before conception. Nonoxynol-9 should be avoided because of the increased risk of viral transmission. Educate on safer sexual practice to minimize the risk of acquiring other sexually transmitted infections.

It is important to be aware of potential interactions between oral contraceptives and antiretrovirals such as boosted protease inhibitors or non-nucleoside reverse transcriptase inhibitors which may decrease efficacy of contraceptives. Alternative or additional methods of birth control should be used. Consult current resources for more information.

3. Educate and counsel about perinatal transmission risks, prevention strategies, and potential effects of HIV or treatment on pregnancy course and outcomes.
4. Assess virological and immunological status.
   - Women with favorable immunologic and virologic characteristics do not require antiretroviral therapy until after the first trimester.
   - Women with unfavorable characteristics may benefit from antiretroviral intervention. Initiation or modification of antiretroviral therapy prior to conception allows the woman to avoid agents with potential fetal toxicity; choose agents effective in reducing risk of perinatal transmission; attain a stable and maximally suppressed maternal viral load; and evaluate and manage therapy-associated side effects which can adversely affect maternal-fetal health outcomes.
   - Efavirenz should be avoided in the first trimester of pregnancy due to possible teratogenicity risk. In women with hepatitis B coinfection, tenofovir would be the preferred nucleoside reverse transcriptase inhibitor (NRTI), in addition to emtricitabine (FTC) or lamivudine (3TC).
5. Assess for and initiate prophylaxis of opportunistic infections and administration of indicated immunizations.
6. Evaluate maternal nutritional status. Initiate a prenatal vitamin supplementation.
7. Screen for psychological and substance abuse disorders. Encourage smoking cessation, and avoiding/minimizing alcohol and illicit substance use.
8. Plan for obstetric consultation if indicated.
9. Provide other standard components of preconception evaluation and management.

Care for HIV NEGATIVE WOMEN with an HIV POSITIVE MALE partner:

1. Assess both partners for acute infection.
2. Assess for and treat any inflammatory genital tract conditions.
3. Initiate or modify antiretroviral medication in the HIV positive partner to achieve an undetectable viral load and to decrease risk of transmission.
4. When possible, all cases should be co-managed with a Fertility expert/Fertility clinic and HIV specialist. For women with an HIV positive partner trying to achieve pregnancy, the ideal is to recommend no unprotected intercourse and be referred to a fertility centre for sperm washing and assisted fertilization. At the present time, sperm washing is only available in Calgary and therefore may be impractical and costly for many couples.
5. If a couple opts not to use assisted fertilization after extensive counseling, the use of timed conception with no unprotected intercourse outside of conception may be cautiously approached. Couples can be advised that the risk of HIV transmission per exposure is about one hundred times lower than the probability of achieving pregnancy.
6. The use of donor sperm may also be considered in some cases and some couples may choose this approach.
7. If pregnancy results from unprotected sex in an HIV-negative female with an HIV-positive partner (serodiscordant couple), the pregnant female needs to inform her pregnancy care provider of the fact the partner is HIV-positive. This female will require monthly HIV antibody testing AND monthly HIV RNA viral load testing until the time of delivery to detect prenatal HIV seroconversion.

Antenatal Care

A. General

- All pregnant women should be offered HIV antibody testing early in the pregnancy after informing them of the test, along with standard prenatal blood tests unless they actively decline such testing.
- Pregnant women at continued high risk for HIV infection [e.g. active injection drug use, HIV-infected sexual partner, multiple sexual partners, sex trade worker, recent history of sexually transmitted infection, history of incarceration, inner city/homeless, aboriginal, individual from HIV endemic region (i.e. sub-saharan Africa, Caribbean), sexual partner with risk factors for HIV] should have repeat testing in late pregnancy. Pregnant

women highly suspect to HIV seroconvert who are in the "window period" should have HIV RNA testing as well. If repeat testing has not been performed by the time the woman presents for delivery, STAT HIV testing should be carried out immediately. For Central and Northern Alberta, on-site Rapid HIV testing is currently at the following hospitals: Edmonton Zone (Royal Alexandra, University of Alberta, Grey Nuns, Misericordia, Sturgeon; and Northern Sites (Queen Elizabeth II (Grande Prairie), Northern Lights Regional Health Centre (Fort McMurray) and Bonnyville Health Centre (Bonnyville)). The Rapid HIV test should be used as indicated by the respective protocol (Rapid HIV Testing Pilot Protocol). For sites without Rapid HIV testing, STAT HIV testing can be arranged by contacting the virologist-on-call.

- HIV positive women with unintended pregnancies should be counseled about all options regarding continuation of the pregnancy.
- Pregnant women who are HIV-infected should receive all regular antenatal care and counseling, including screening for other sexually transmitted infections, cervical cytological abnormalities, substance abuse, psychological disorders, and social supports. Ultrasonography should be performed as per usual routine prenatal care including a detailed obstetrical ultrasound at 18-19 weeks gestation with follow-up ultrasound to assess growth. Referral to an obstetrician with expertise in the unique aspects of care of HIV positive women is recommended.
- Evaluate maternal nutritional status. Initiate a prenatal vitamin supplementation as per current recommendations on routine pregnancy care.
- Administer medical immunizations if not yet received (influenza, pneumococcal, hepatitis B vaccines).
- Site of Care: Every effort should be made to ensure pregnant women deliver in a site with expertise in high risk deliveries. In the Edmonton Zone these sites include the Royal Alexandra Hospital, the Grey Nuns Community Hospital and the Misericordia Community Hospital.
- The Medical Officer of Health (MOH) should be notified of any woman who is HIV-positive and pregnant. This will ensure that Public Health and Community follow-up is initiated.

B. Multidisciplinary Team Care

- HIV positive women should be assessed by an Adult Infectious Diseases (ID) physician early in the pregnancy. The infectious diseases physician and HIV pharmacist, in concert with the obstetrician, and following an informed discussion with the patient, will consider antiretroviral therapy based on maternal indication, as well as the most current knowledge regarding prevention of HIV transmission to the fetus. HIV resistance testing (genotyping) should be considered for all pregnant women (see Appendix A, Antiretroviral Considerations in Pregnancy and Appendix B, HIV in Pregnancy Treatment Algorithm).
- Every effort should be made to assist the pregnant female with medication adherence. This includes offering: bubble-packed medications, providing a beeper, frequent telephone follow-ups, monthly clinic visits, directly observed therapy (DOT) and possibly home visits by Public Health.
- Close communication amongst the woman's infectious diseases physician, pediatric infectious diseases physician, obstetrician, primary care physician, public health nurse and pharmacist (i.e. through copies of letters) is imperative. Information should include:
  - Current antiretroviral therapy;
  - Adherence to therapy;
  - Treatment response (most recent CD_4 count and HIV viral load);
  - Co-infection with hepatitis C and/or B;
  - Anticipated route of delivery (scheduled cesarean section, vaginal birth, induction, etc);
  - Anticipated hospital where delivery will occur;
  - Plan regarding continuation of antiretrovirals for the mother during labour and after delivery;
  - Whenever possible, and recognizing that late stage developments could alter this plan, the pediatric infectious diseases physician most involved should indicate the treatment plan for the infant before the anticipated due date.
- Records should be faxed to the Caseroom where the woman is anticipated to deliver and kept in a specified location. Any other measures that may facilitate communication should be considered, e.g. providing a copy of important information directly to the patient as a wallet card or booklet.

C. Laboratory Investigations

- Prenatal testing results can be obtained by reviewing NetCare, and if results are not available, by calling the ProvLab, Edmonton site (780-407-7121) and identifying yourself as a nurse or physician caring for the patient.
- Repeat HIV testing in high-risk HIV negative mothers during pregnancy and at the time of delivery is recommended.
- Monitor CD_4 cell count and viral load at diagnosis. The optimal testing interval is every 4-6 weeks. Include the word "pregnant" on the lab requisition. This will allow for timely changes in antiretroviral therapy if warranted.
- HIV resistance testing (genotyping) should be considered for all pregnant women (see Appendix A, Antiretroviral Considerations in Pregnancy and Appendix B, HIV in Pregnancy Treatment Algorithm).
- For patients likely infected with non-B HIV clades (HIV source can include either acquisition from outside of North America, e.g. endemic Africa, Asia and also regions in Canada where non-B clades are circulating), HIV RNA viral load might not be accurately quantified using the routine HIV viral load assay at the ProvLab. Consideration can be given to ordering HIV clade and RNA viral loads using alternate methods at the National Laboratory for HIV Reference Services, PHAS, through the ProvLab. Reference HIV viral load testing can be arranged by contacting the virologist-on-call if there is residual plasma sample at the ProvLab. HIV clade testing requires special collection of a whole blood sample and a separate requisition for HIV subtype testing.
- Monitor for toxic effects related to the particular antiretroviral therapy being used (e.g. hematologic, hepatic, renal, pancreatic, or metabolic effects). Monitoring should begin 2 weeks after initiation of antiretroviral therapy and monthly thereafter.

D. Other Medical Therapy

- Antiretroviral Therapy: (see Appendix A, Antiretroviral Considerations in Pregnancy and Appendix B, HIV in Pregnancy Treatment Algorithm).
- For women who are immunocompromised, offer prophylaxis against *Pneumocystis jiroveci* pneumonia (PJP), *Mycobacterium avium* complex (MAC), and other prophylactic therapies according to usual adult guidelines. Initiate PJP prophylaxis if CD_4 count is less than 200 cells/μL with trimethoprim 160 mg/sulfamethoxazole 800 mg PO daily (e.g. Septra® DS 1 tablet PO daily). If used in patients in the first trimester, add folic acid 5 mg daily to help prevent neural tube defects. Trimethoprim/sulfamethoxazole therapy during the 3rd trimester can be continued with caution. While there is a theoretical risk of kernicterus in the newborn, this is a rare occurrence and the benefit outweighs the risk in this group of women.
- Manage any complications, including opportunistic infections with assistance from Infectious Diseases.
- Ultrasonography should be performed as per routine prenatal care and used to assess fetal growth in the second and third trimester in women on antiretroviral therapy and for other obstetrical indications.

E. Procedures

- Avoid invasive procedures such as amniocentesis, internal fetal monitoring and obtaining fetal scalp gases unless the benefit outweighs the risk.

F. Mode of Delivery

- Discuss the mode of delivery with the woman. All HIV-infected women should be made aware of evidence that an elective cesarean section may decrease the likelihood of perinatal transmission in women who are not taking antiretroviral therapy and those receiving monotherapy. According to current consensus, scheduled cesarean section at 38 weeks gestation should be considered if the most recent viral load is greater than 1000 copies/mL. If a woman is receiving optimal therapy and has achieved complete suppression of the plasma viral load, then vertical transmission is considered unlikely and there is no documented advantage to cesarean section.
- If the Infectious Diseases consultant requests a prioritized quantitative HIV viral load near the time of delivery, he or she should call the virologist on-call to request that the viral load study be included in the next "run", providing the patient's identification and the reason for requiring a rapid turn-around time. Please call the virologist-on-call if there is any concern about the turn-around time.

Intrapartum Care

A. General

- Staff in Labour & Delivery should refer to the prenatal record and information records on the patient kept on the unit in the designated HIV location. If there is a letter from Infectious Diseases available, staff may initiate medications according to the protocol. If not, notify Adult Infectious Disease on call. If a woman presents at a different facility than planned, staff are encouraged to call the intended delivery facility for this information to be faxed to the unit.
- Women are managed utilizing the treatment algorithm found in Appendix B HIV in Pregnancy Treatment Algorithm and following the pre-printed orders for care found in Appendix C Patient Care Orders: Maternal Delivery Orders for HIV Positive Women or Unknown HIV Status and High Risk.
- In the event that a woman receives part of the IV Zidovudine Protocol and other antiretrovirals at the onset of labour, and does not establish herself in labour, the medications should be discontinued and re-established when labour commences. In the interim, she should continue to take her routine oral antiretrovirals.

B. Management of Patient for a Vaginal Birth

- Routine precautions should be undertaken for blood and body fluid protection. This includes gown, mask, eye protection and gloves for all care providers at time of birth.
- Epidurals are not contraindicated.
- Avoid rupture of the membranes unless obstetrically indicated. With the exception of elective C-section, invasive procedures such as fetal spiral electrodes, fetal scalp sampling, intrauterine pressure catheters, episiotomy and vacuum extraction/forceps deliveries may enhance risk for transmission and are not recommended.
- Use of vacuum or forceps should be carefully evaluated by weighing the risks and benefits of the clinical situation, keeping in mind that interventional procedures could enhance the risk for transmission.

C. Management of Patient for a Cesarean Birth

- Elective cesarean delivery should continue to be recommended for women not on therapy or on antiretroviral therapy who have HIV RNA levels greater than 1,000 copies/mL near delivery
- Elective cesarean delivery should not be routinely provided for women on therapy who have HIV RNA less than 1,000 copies/mL, unless they choose this procedure after thorough counselling regarding uncertain benefits and known risks or for other routine obstetrical indications.
- Recommendation regarding timing of elective cesarean section is that it be done at 38+ weeks gestation determined by the best clinical estimate of dates and avoiding amniocentesis.
- It is unclear whether there is any benefit to performing an emergency C-section for women that present with ruptured membranes or advanced labour. Management of such women must be individualized based on duration of rupture, progress in labour, plasma HIV-1 RNA level, current antiretroviral therapy and other clinical factors. There is no clear evidence as to when the loss of benefit of C-section occurs in relation to the onset of ruptured membranes.
- Medication recommendations include:
  - IV zidovudine should begin 3 hours prior to surgery.
  - Other antenatal oral antiretroviral medications should be continued without interruption.
  - Morbidity is potentially increased due to maternal infections, therefore routine perioperative antimicrobial prophylaxis should be used as per current recommendations for cesarean section.

Postnatal Care

- Comprehensive care and support services are important and should be coordinated between Obstetrics, Infectious Diseases, Pediatrics and other health care providers with involvement of Public Health, Social Services and other agencies where necessary to ensure that both mother and child receive appropriate medical follow-up in the post-natal period.
- The Medical Officer of Health should be notified of any woman who is pregnant and whose HIV infection was not detected through prenatal screening (i.e. newly diagnosed HIV positive at the time of delivery). This will ensure that appropriate Public Health and community follow-up is initiated.
- HIV is present in breast milk and prospective studies have demonstrated breastfeeding to be independently associated with substantial risk of HIV transmission. Exclusive formula feeding should be strongly recommended and provisions made to ensure availability of infant formula (available free of charge through the Northern Alberta HIV Program).
- No specific monitoring is required with respect to HIV disease for the mother. Mothers should continue with prenatal antiretroviral therapy unless otherwise advised by the Adult Infectious Diseases and follow-up should be arranged with an Infectious Diseases physician following discharge. She should resume the therapeutic antiretroviral regimen as soon as she can tolerate oral intake, unless otherwise directed by her Infectious Diseases Specialist.
- A longer-than-average hospital stay may be required to ensure satisfactory recovery and also to establish that the infant is tolerating therapy, is feeding well and is gaining weight.
- Women should be counselled about the fact that the physical changes of the postnatal period, as well as the stresses and demands of caring for a new baby can make adherence to antiretroviral regimens more difficult and additional support may be needed to maintain good adherence. The health care provider should be vigilant for any issues such as signs of depression, cultural factors, homelessness and addictions which may impact adherence.
- Contraception counselling and planning should ideally occur before hospital discharge. Care must be taken to avoid drug interactions associated with oral contraceptive medications. Some antiretrovirals may decrease the serum concentrations of ethinyl estradiol containing oral contraceptives, thus making them less effective. An alternate form of contraception such as concurrent condom use or use of an intrauterine contraception device is recommended. With progestin only preparations such as Micronor® or Depo-Provera®, there are minimal interactions and these can be safely given with antiretrovirals. Consult a current reference for specific interactions.
- All women should receive comprehensive health care services that continue after pregnancy for their own medical care and for assistance with family planning and contraception. This is a good time to review immunization status and update vaccines, assess the need for prophylaxis against opportunistic infections and reemphasize safer sex practices.

Appendix A

Antiretroviral Considerations in Pregnancy

- Perform resistance testing (HIV genotyping) at baseline unless the viral load is fully suppressed (less than 40 copies/mL) while on therapy at the first visit. In general, genotyping can be reliably performed if the viral load is greater than 500 to 1000 copies/mL.
- Decisions regarding antiretroviral therapy should be made by a physician expert in HIV care, and preferably in conjunction with an HIV pharmacist, taking into account past treatment history, results of resistance testing, hepatitis B coinfection status, potential teratogenicity of antiretroviral drugs, and history of adherence problems.
- Use suppressive combination antiretroviral therapy which usually consists of 3 active drugs. Unless there is a specific contraindication, at least one of the drugs should have high placental transfer to the fetus (e.g. agents such as abacavir, zidovudine, tenofovir, lamivudine and emtricitabine). The goal of therapy is to suppress the viral load (HIV RNA) to less than 40 copies/mL during the pregnancy and especially at the time of delivery.
- Consult current resources for more information about antiretroviral use in pregnancy. Preferred nucleoside reverse transcriptase inhibitors are zidovudine, lamivudine and abacavir. There is also increasing evidence to support the use of tenofovir and emtricitabine. Due to increased drug toxicity, stavudine and didanosine should only be considered in special circumstances when other antiretrovirals are not suitable.
- The preferred non-nucleoside reverse transcriptase inhibitor is nevirapine (caution in women with baseline CD4 counts > 250 cells/uL). Efavirenz should be avoided, especially in the first trimester.
- The preferred protease inhibitors are atazanavir/ritonavir and lopinavir/ritonavir. Alternative agents include darunavir/ritonavir or saquinavir/ritonavir. Nelfinavir and indinavir/ritonavir should only be considered in special circumstances when other antiretrovirals are not suitable.
- HLA-B*5701 should be ordered if abacavir is being considered.
- The HIV viral load is monitored every 4-6 weeks during pregnancy (HIV-RNA).
- If drug resistance is suspected or known, a regimen containing 3 active drugs is recommended.
- If a pregnant woman is stable on suppressive drug therapy prior to pregnancy, treatment may be continued even in first trimester of therapy. Ensure that the regimen is the least toxic and teratogenic possible.
- If the patient becomes pregnant while on efavirenz, she should be made aware of the small additional risk of adverse fetal outcome.
- Women who have a history of zidovudine resistance and are on antiretroviral regimens that does not include zidovudine should still receive intrapartum IV zidovudine and their infants should receive oral zidovudine in addition to other antiretrovirals as recommended by Pediatric Infectious Diseases.
- Adherence to treatment is key to the success of therapy. Make arrangements for daily observed therapy if necessary. Provide tools and necessary supports to assist with adherence (beepers, bubble-packing, dosettes, family supports, frequent phone calls, home visits).

Appendix B

HIV in Pregnancy Treatment Algorithm 5 Scenarios

Please refer to Patient Care Order: Maternal Delivery orders for HIV Positive Women or Unknown HIV Status and High Risk orders for all Scenarios.
Appendix C

Please refer to Patient Care Order: Infant of HIV Positive Mother for all Scenarios.
Appendix E

SCENARIO 1

- HIV positive, history of antenatal antiretroviral use
- Presenting in labour
- Viral load less than 1,000 copies/mL near estimated time of delivery (in past month)

Mother	Baby
▪ **Continue on antepartum oral antiretrovirals during labour.** ▪ Review Adult Infectious Diseases prenatal letter on unit regarding peri-partum antiretrovirals, indication for post-partum antiretrovirals and follow-up care for a specific patient. ▪ **IV Zidovudine Maternal Protocol.*** ▪ Proceed with vaginal delivery, reserving C-section for obstetrical indications.	▪ Consult Pediatric Infectious Diseases. ▪ **Initiate PO/IV zidovudine x 6 weeks as soon as possible and no later than 6 hours after birth.**

Scenario 2

- HIV positive, history of antenatal antiretroviral use
- Viral load greater than or equal to 1,000 copies/mL near estimated delivery date

Mother	Baby

▪ *Note: A **scheduled C-section** at 38 weeks gestation is recommended.*
  ○ *Protocol drugs should be administered 3 hours prior to surgery.*
  ○ *Use of routine prophylaxis antibiotics at time of delivery is recommended.*
	▪ Consult Pediatric Infectious Diseases for final orders first.
	▪ **Immediately (as soon as possible and no later than 6 hours after birth)** start antiretroviral prophylaxis (See Appendix E):
	▪ **All babies are to receive:**
	  ○ **PO/IV zidovudine x 6 weeks**
	▪ **At the discretion of Pediatric Infectious Diseases, babies will usually receive additional drugs such as:**
	  ○ **PO lamivudine (3TC®)**
	  ○ **PO nelfinavir**
	  ○ **PO nevirapine**

▪ **If patient with unknown or elevated HIV viral load presents with ruptured membranes or is in labour, the decision to proceed with an emergency C-section versus allowing for a vaginal delivery should take into account duration of ruptured membranes, progress in labour, HIV viral load and current antiretroviral therapy. There is no clear benefit in decreasing transmission with emergency C-section or evidence when the loss of benefit occurs.**
▪ **In the event of an unexpected vaginal birth continue on antepartum oral antiretrovirals during labour.**
▪ Review Adult Infectious Diseases prenatal letter on unit regarding peri-partum antiretrovirals and indication for post-partum antiretrovirals.
▪ Unless otherwise stated in Adult Infectious Diseases prenatal letter, all women (cesarean section or vaginal) who are delivering should receive the following therapies:
  ○ **IV Zidovudine Maternal Protocol***
  ○ **Continue on oral antepartum antiretrovirals**	

* Note: If antepartum regimen contains stavudine (d4T or Zerit®), discontinue stavudine during IV zidovudine infusion secondary to an antagonistic drug interaction with zidovudine.

Scenario 3

- HIV positive, NO history of antenatal antiretrovirals,
- NO IV zidovudine given intra-partum.
- Vaginal delivery

Mother	Baby
▪ Consult Adult Infectious Diseases about indication for post-partum antiretrovirals, follow-up appointment, etc.	▪ Consult Pediatric Infectious Diseases for final orders first. ▪ **IMMEDIATELY (as soon as possible and no later than 6 hours after birth)** start drug prophylaxis which *may* consist of (See Appendix E): ▪ **All babies are to receive:** ○ **PO/IV zidovudine x 6 weeks** ▪ **At the discretion of Pediatric Infectious Diseases, babies will usually receive additional drugs such as:** ○ **PO lamivudine (3TC®)** ○ **PO nelfinavir** ○ **PO nevirapine**

Scenario 4

- HIV positive, known or suspected history of antiretroviral drug resistance (includes zidovudine resistance).

Mother	Baby
▪ **Continue on antepartum oral antiretrovirals during labour** ▪ Review Adult Infectious Diseases prenatal letter on unit regarding peri-partum antiretrovirals, indication for post-partum antiretrovirals and follow-up care for a specific patient. ▪ **IV Zidovudine Maternal Protocol*** (even if mother has a history of zidovudine resistance, IV zidovudine should be administered). ▪ Scheduled cesarean section delivery if viral load is greater than1,000 copies/mL.	▪ **Initiate PO/IV zidovudine x 6 weeks as soon as possible and no later than 6 hours after birth.** ▪ Consult Pediatric Infectious Diseases (**other antiretroviral drugs will usually be required** depending on mother's drug resistance patterns and viral load close to the time of delivery).

Note: Please see **Scenario 5** on following page (Unknown status or HIV-negative in early pregnancy OR recent high risk activities).

* Note: If antepartum regimen contains stavudine (d4T or Zerit®), discontinue stavudine during IV zidovudine infusion secondary to an antagonistic drug interaction with zidovudine.

Scenario 5

- Unknown HIV status or HIV-negative in early pregnancy,
- Recent high-risk activities
  - Active injection drug use, HIV-infected sexual partner, multiple sexual partners, sex trade worker, recent history of sexually transmitted infection, history of incarceration, inner city/homeless, aboriginal, individual from HIV endemic region [i.e. sub-Saharan Africa, Caribbean], sexual partner with risk factors for HIV *(refer to page 3 – Antenatal Care).*
  - Highly suspect for HIV seroconversion and/or in "window period"- Consult Adult Infectious Diseases on-call. In this case HIV-RNA PCR testing may be done in addition to the STAT HIV antibodies test.

Mother	Baby
▪ STAT HIV antibodies test (contact virologist on-call at Provincial Lab at 780-407-8822) or use Rapid HIV Test if available at site. ▪ HIV RNA PCR (Quantitative) – to be done only if HIV antibodies tested as positive ▪ HCV Antibody (if unknown) ▪ HBsAg ▪ Syphilis serology (collect 5 mL in SST serum Vacutainer) ▪ *If the maternal HIV status is pending, consider immediate administration of IV zidovudine in the interim with consent of mother (see IV Zidovudine Maternal Protocol)* ▪ **If mother is HIV positive, consult Adult Infectious Diseases immediately.** ▪ **If mother is HIV positive and still in labour, immediately initiate IV Zidovudine Maternal Protocol.** ▪ **If patient is newly diagnosed with HIV and presents with ruptured membranes or is in labour, the decision to proceed with an emergency C-section versus allowing for a vaginal delivery should take into account duration of ruptured membranes, progress in labour and HIV viral load if available. There is no clear benefit in decreasing transmission with emergency C-section or evidence when the loss of benefit occurs.**	▪ If Mother's HIV test is negative at delivery (HIV Negative), then no therapy is required. ▪ *If maternal HIV test is pending, consider immediate administration of PO/IV zidovudine in the interim.* ▪ **If Mother's HIV test is positive (HIV Positive), initiate PO/IV zidovudine x 6 weeks IMMEDIATELY (as soon as possible and no later than 6 hours after birth).** ▪ **Consult Pediatric Infectious Diseases immediately. They will determine infant treatment as in Scenario 2 or 3.** ▪ **Consider ordering a baseline HIV proviral DNA to determine possible vertical transmission (collect in EDTA tube; specimens are sent to Ottawa).** ▪ **If maternal syphilis serology is positive, also perform testing on the infant.** Collect at least 2 mL blood in a pediatric serum Vacutainer. Must write "NEWBORN" on requisition in BIG letters.

APPENDIX C

Patient Care Orders:

Maternal Delivery Orders for HIV Positive Women or Unknown HIV Status and High Risk

1. All orders must be completed and signed by the physician or nurse practitioner All co-signatures must be timed and dated within **24 hours.**
2. Orders may be deleted by stroking the order out and initialling the entry or by leaving prompt blank (boxes and / or lines).
3. Pre-printed orders may be initiated by (√). Box not checked will not be initiated.

Allergies _____

Weight _____

Date / Time	
	1. Unknown HIV status (HIV labs on admission):(no prenatal HIV test result OR possibility of ongoing HIV risk since prenatal HIV test) ☐ Stat HIV antibodies test (page virologist on call from Provincial Lab at UAH switchboard 780-407-8822) ☐ Rapid HIV test where indicated in cases of high risk, unknown HIV status (where available) ☐ HIV RNA PCR (Quantitative) – to be done only if HIV antibodies tested as positive. Collect 3 mL per tube in two EDTA tubes (lavender top). ☐ Consult Adult Infectious Diseases on high risk suspected HIV seroconversion cases **Unknown status and high risk (additional labs on admission):** ☐ CBC, differential, AST, ALT, creatinine, glucose, bilirubin ☐ HCV Antibody if unknown ☐ HBsAg ☐ Syphilis serology
	2. These orders apply to mothers known to be HIV Positive ☐ Consult Adult Infectious Diseases Clinic letter on the ward for antepartum and postpartum orders. If unable to obtain letter, consult Infectious Disease Physician on call. ☐ **Notify:** HIV Nurse with Northern Alberta Program, RAH site **(780-735-5340 or 780-735-4811)** ☐ Continue antepartum oral antiretroviral therapy during active labour as specified: ○ ○ ☐ Discontinue stavudine during IV zidovudine infusion if patient's antepartum regimen contained stavudine (d4T or ZERIT®)
	3. Labs on admission for HIV positive women ☐ CBC, differential, AST, ALT, creatinine, glucose, bilirubin ☐ HCV Antibody if unknown ☐ HBsAg ☐ Syphilis serology ☐ CD_4 cell count (only if not done in the past 3 months) ☐ STAT HIV RNA PCR (Quantitative). Discuss the need for 'STAT' with the virologist on call at 780-407-8822. Collect 3 mL per tube in two EDTA tubes (lavender top). Use HIV Viral Load Test requisition.
	4. Establish IV (5% dextrose in water, 5% dextrose in normal saline, normal saline) as soon as possible at time of: ☐ Rupture of membranes OR ☐ Onset of labour (greater than 3 cm dilated) OR ☐ Greater than or equal to 3 hours prior to Cesarean Section ☐ Start of induction process
	5. Administer intravenous zidovudine (AZT, ZDV, RETROVIR®) as soon as active labour is established OR at the start of the induction process OR greater than or equal to 3 hours prior to Cesarean Section. ☐ Loading dose (2 mg/kg):_____ milligrams IV over 1 hour, followed by: ☐ Continuous infusion (1 mg/kg/hour):_____ milligrams/hour IV until the cord is clamped. ☐ Discontinue the above medication at time of clamping of the umbilical cord. **Note:** If labour stops and infusion is discontinued for more than 6 hours, re-administer loading dose and resume continuous infusion when labour recommences.
	Prescriber's Signature: _____
	Prescriber's Printed Name: _____

CH-0000 July 21, 2014 Pink – Chart White – Pharmacy **PAGE 1 of 2**

APPENDIX C

Patient Care Orders:

Maternal Delivery Orders for HIV Positive Women or Unknown HIV Status and High Risk

1. All orders must be completed and signed by the physician or nurse practitioner All co-signatures must be timed and dated within **24 hours.**
2. Orders may be deleted by stroking the order out and initialling the entry or by leaving prompt blank (boxes and / or lines).
3. Pre-printed orders may be initiated by (√). Box not checked will not be initiated.

Allergies _____

Weight _____

Date / Time	
	6. General Management of Labour ▪ Routine practice applies; gown, mask, eye protection and double gloves. ▪ No artificial rupture of membranes unless absolutely necessary for obstetrical management. ▪ Rupture of membranes greater than or equal to 4 hours should be avoided if possible. ▪ Avoid the use of fetal spiral electrodes, fetal scalp sampling, intrauterine pressure catheter, and assisted delivery with vacuum/forceps unless benefits exceed risks. ▪ Epidural anesthesia is not contraindicated.
	7. Post Partum ☐ **Breastfeeding is contraindicated.** ☐ Notify Medical Officer of Health **(780-342-0185 or 780-433-3940)** during daytime hours ONLY if a new HIV positive case is identified during labour and delivery **Antiretroviral Regimen** ☐ Refer to Adult Infectious Diseases consult letter on the ward and select the appropriate option. **Options include:** ☐ Discontinue all antiretrovirals after delivery. ☐ Resume antepartum antiretrovirals after delivery. Specify orders: _____ _____ _____ **Follow-up** ☐ Primary obstetric, pediatric and HIV specialty care (See Appendix H) ☐ Family Planning Services (Tubal ligation, DEPO-PROVERA®, intrauterine contraception device, etc.) ☐ Social Work Consult ☐ Mental Health Services ☐ Addiction treatment (e.g. if experiencing opiate withdrawal) ☐ Coordination of care through case management (child care, respite care, assistance with basic life needs, legal and advocacy services.) ☐ Teaching re: pediatric medication to mother/caregiver
	Prescriber's Signature:
	Prescriber's Printed Name: _____

CH-0000 July 21, 2014 Pink – Chart White – Pharmacy **PAGE 2 of 2**

Appendix D

Hospital Maternal HIV Positive Checklist

Labour & Delivery	Initials
Ensure that maximal confidentiality of maternal HIV status is maintained.	
Determine if HIV-infected woman is taking antiretroviral therapy during the current pregnancy and the most recent viral load measurement.	
Check for Adult Infectious Diseases physician antepartum letter on file. If there is no letter outlining maternal perinatal antiretrovirals, contact switchboard to page Adult Infectious Diseases on call. (UAH: 780-407-8822; RAH: 780-735-4111).	
Contact the Northern Alberta Program at the RAH site 780-735-5340 or 780-735-4811. This is a confidential line and you may leave a message with mother's name and location of mom and baby.	
Initiate intrapartum IV zidovudine (see Appendix C, J) during labour and delivery to the mother regardless of antepartum antiretroviral regimen or mode of delivery. Additional antiretrovirals for the HIV-infected woman may be recommended by the Adult Infectious Diseases physician. See letter on file.	
If applicable, continue HIV-infected woman's antepartum antiretroviral regimen wherever possible throughout labour/delivery and following delivery with the exception of stavudine (d4T, Zerit®). (See Treatment Algorithm Appendix B).	
Routine Precautions: Ensure that the routine blood and body fluid precautions are observed. No additional precautions are required.	
Breast feeding is contraindicated.	

Postpartum – Prior to Discharge	Initials
Ensure that maximal confidentiality of maternal HIV status is maintained.	
Contact designated Public Health Pre-natal HIV nurse prior to hospital discharge.	
Ensure arrangements for follow-up of the mother and baby are made with Adult and Pediatric Infectious Diseases physicians.	
Ensure that the prescription for 6 weeks of discharge infant medication is filled at the RAH or UAH outpatient pharmacy and that the mother/caregiver has the ordered drugs prior to discharge. If Rexall is closed, contact the hospital inpatient pharmacy to make arrangements for a 1-2 week supply of antiretrovirals. The remainder of the supply should be obtained from Rexall Pharmacy • **UAH Rexall Outpatient Pharmacy** is open Monday to Friday 0800-1800hrs, Saturday 0800–1300 hrs **Phone:** 780-407-6990, **Fax:** 780-407-1090 • **RAH Rexall Outpatient Pharmacy** is open Monday to Friday 0900-1700hrs **Phone:** 780-735-5296, **Fax:** 780-735-5258	
Ensure that the mother has received free formula and syringes for infant medications.	
Supportive management of breast engorgement and breast care. **Breastfeeding is contraindicated.**	
[2] Contraceptive counseling and planning should be provided to mother prior to discharge and if not possible arrangements should be made for follow-up of this as soon as possible after discharge.	

[2] *At Covenant Health Group facilities, we must be balanced with the moral considerations and prohibitions presented in the Health Ethics Guide, the foundational ethical framework used in Catholic healthcare institutions, including Covenant. The principles of legitimate cooperation may apply in some instances. An ethics consult is recommended to help interpret specific cases where this applies.*

(Leave 5/8" border for three-hole punch on left side)

Patient Care Orders:
Infant of HIV Positive Mother

Appendix E

1. All orders must be completed and signed by the physician or nurse practitioner All co-signatures must be timed and dated within **24 hours.**
2. Orders may be deleted by stroking the order out and initialling the entry or by leaving prompt blank (boxes and / or lines).
3. Pre-printed orders may be initiated by (√). Box not checked will not be initiated.

Allergies _____

Birth Weight _____

DATE / TIME	INFANT ORDERS
	1. Routine Precautions: Wash infant prior to any invasive procedures; IM injection venipunctures.
	2. **Breastfeeding is contraindicated.**
	3. Page Pediatric Infectious Diseases on call re: bloodwork and medications (UAH switchboard: 780-407-8822).
	4. Obtain verbal consent for HIV screening of baby. Document on patient record.
	5. LABS:
	• Check maternal Hepatitis B status. If mother Hepatitis B surface antigen positive (HBsAg+), follow Hepatitis B prophylaxis standing orders or consult the infant's physician.
	• CBC, differential.
	• HIV RNA PCR, (Quantitative). Collect 2-3 mL blood in 1 EDTA tube (lavender top).
	• Urine CMV (use sterile container) and throat swab for CMV viral culture (use universal transport medium).
	6. MEDICATIONS:
	zidovudine (ZDV, AZT®) is given to ALL infants born to HIV-positive mothers.
	• Begin zidovudine **immediately (ideally within 6 hours of delivery).** To minimize delay, antiretrovirals can be started prior to doing bloodwork.
	• Oral therapy is preferred but IV route may be used if infant unable to tolerate oral feeds.
	☐ Infants greater than or equal to 35 weeks:
	❑ PO zidovudine 4 mg/kg/dose: _____mg PO every 12 hours for 6 weeks. **OR**
	❑ IV zidovudine 3 mg/kg/dose: _____mg IV every 12 hours for 6 weeks.
	☐ Infants 30-34 weeks:
	❑ PO zidovudine 2 mg/kg/dose: _____mg PO every 12 hours for 2 weeks, then 3 mg/kg/dose every 12 hours until 6 weeks of age. **OR**
	❑ IV zidovudine 1.5 mg/kg/dose: _____mg IV every 12 hours for 2 weeks, then 2.3 mg/kg/dose every 12 hours until 6 weeks of age.
	☐ Infants less than 30 weeks:
	❑ PO zidovudine 2 mg/kg/dose: _____mg PO every 12 hours for 4 weeks, then 3 mg/kg/dose every 12 hours until 6 weeks of age. **OR**
	❑ IV zidovudine 1.5 mg/kg/dose: _____mg IV every 12 hours for 4 weeks, then 2.3 mg/kg/dose every 12 hours until 6 weeks of age.
	Prescriber's Signature: _____
	Prescriber's Printed Name: _____

CH-0000 July 21, 2014 Pink – Chart White – Pharmacy Page 1 of 2

Appendix E

Patient Care Orders:
Infant of HIV Positive Mother

(Leave 5/8" border for three-hole punch on left side)

1. All orders must be completed and signed by the physician or nurse practitioner. All co-signatures must be timed and dated within **24 hours.**
2. Orders may be deleted by stroking the order out and initialling the entry or by leaving prompt blank (boxes and / or lines).
3. Pre-printed orders may be initiated by (√). Box not checked will not be initiated.

Allergies _____

Birth Weight _____

Date / Time	Infant orders
	Optional additional medications (may be ordered by Pediatric Infectious Diseases, depending on maternal risk/resistance).
	nevirapine 10 mg/mL oral syrup. Contact Pharmacy for "*Special Access" consent form.* See Appendix I, L
	Three-dose PO nevirapine (prophylactic dose for HIV prevention)- select dose below ❑ Birth weight less than 1.5 kg: 2 mg/**kg per dose:** _____ mg per dose given PO (note: **dose per kg** for this weight) ❑ Birth weight 1.5-2 kg: 8 mg **per dose** given PO ❑ Birth weight greater than 2 kg: 12 mg **per dose** given PO For all weights, 3 doses are given in the first week of life as follows: • 1st dose at birth (ideally within 6 hours of birth) • 2nd dose day 2 (48 hours after the 1st dose) • 3rd dose day 6 (96 hours after the 2nd dose)
	lamiVUDine (3TC®) 10 mg/mL oral solution. See Appendix I, M
	❑ lamiVUDine 2 mg/kg/dose: _____mg PO every 12 hours for _____ weeks **Note**: If lamivudine is prescribed beyond 4 weeks of age, the dose should be increased to 4 mg/kg/dose PO every 12 hours at **4 weeks of age**. *Duration will be determined by Pediatric Infectious Diseases physician*
	didanosine (ddI) 10 mg/mL oral solution (reconstituted from 4 g bottles). See Appendix I, O.
	❑ didanosine 50 mg/m²/dose: _____mg PO every 12 hours for _____weeks (give 1 hour before or 2 hours after feeds). *Duration will be determined by Pediatric Infectious Diseases physician* *Contact Pharmacy for "Special Access" consent form.*
	nelfinavir 250 mg oral tablet. See Appendix I, N **for instructions on making an oral liquid.**
	nelfinavir dosing - *Duration will be determined by Pediatric Infectious Diseases physician* ❑ Birth weight less than 1.5 kg: 50 mg/**kg per dose** _____ mg per dose every 12 hours given PO for ____ weeks(note: **dose per kg** for this weight) ❑ Birth weight 1.5 to 2.0 kg: 100 mg **per dose** every 12 hours given PO for ____weeks ❑ Birth weight 2.1 to 3.0 kg: 150 mg **per dose** every 12 hours given PO for ____ weeks ❑ Birth weight greater than 3.0 kg: 200 mg **per dose** every 12 hours given PO for ____ weeks
	Prescriber's Signature: _____
	Prescriber's Printed Name: _____

D O N O T W R I T E I N T H I S S P A C E

CH-0000 July 21, 2014 Pink – Chart White – Pharmacy Page 2 of 2

Appendix F

Hospital Checklist – Infant
Born to HIV Positive Women

Infants	Initials
Provide HIV antiretroviral prophylaxis to the infant <u>immediately</u>, no later than 6 hours post delivery. (See Treatment Algorithm, Appendix B and E for specific drug recommendations).	
Ensure that maximal confidentiality of maternal HIV status is maintained.	
Contact Pediatric Infectious Disease regarding the delivery 780-248-5540. After hours, call UAH switchboard 780-407-8822 to page the Pediatric Infectious Diseases physician on call. This service will determine the antiretroviral regimen to be used in the infant and they will be involved in the long-term follow up of the infant.	
Contact the Northern Alberta Program RAH site at 780-735-5340 or 780-735-4811. This is a confidential line and you may leave a message with mother's name and location of mom and baby.	
Contact Public Health, HIV Prenatal Nurse Designate at 780-342-2322 to ensure that the infant receives a 6-week supply of the medication, required syringes, formula and appropriate follow-up.	
Routine Precautions: Ensure that routine blood and body fluid precautions are observed. Do admission bath as soon as possible after delivery once infant's temperature has stabilized. **<u>Bathe infant with soap and water to remove maternal blood or amniotic fluid prior to intramuscular injections or blood sampling.</u>** Gloves should be worn to handle baby prior to bathing.	
<u>Breastfeeding is contraindicated.</u>	
Obtain verbal consent for HIV screening of baby and document on record.	
Ensure laboratory tests are done.	
Ensure that the prescription for 6 weeks of discharge infant medication is filled at the RAH or UAH outpatient pharmacy and that the mother/caregiver has the ordered drugs prior to discharge. If Rexall is closed, contact the hospital inpatient pharmacy to make arrangements for a 1-2 week supply of antiretrovirals. The remainder of the supply should be obtained from Rexall Pharmacy. • **UAH Rexall Outpatient Pharmacy** is open Monday-Friday 0800-1800 hrs, Saturday 0800-1300 hrs. Phone: 780-407-6990, Fax: 780-407-1090. • **RAH Rexall Outpatient Pharmacy** is open Monday to Friday 0900-1700 hrs. Phone: 780-735-5296, Fax: 780-735-5258.	
Ensure mother or caregiver has a 6-week supply of discharge medications.	
Ensure mother or caregiver has a supply of oral, amber-coloured syringes (approximately 50).	
Ensure the baby will have an adequate supply of formula. Contact Public Health, HIV Prenatal Nurse Designate at 780-342-2322 to confirm if formula has been given.	
Ensure the follow up appointment has been made for baby with the Pediatric Infection Diseases Specialist (780-248-5540) at 2 weeks of age.	
Ensure the mother or caregiver has been given a list of contact phone numbers as needed.	
Prior to discharge review with the mother or caregiver the Pediatric Patient Education Sheets for the medication that the infant will be receiving. (See Appendices K-O). Document discharge teaching on mother's record.	
Document discharge medication on Provincial Notice of Birth for communication to the Community Healthy Beginnings Program.	

Appendix G

Public Health HIV/Pregnancy Checklist

Patient Name: _____ Date of Birth: _____ EDC: _____
Address: _____ Phone: _____ PHN: _____
Baby Name: _____ Delivery Date: _____ Allergies: _____
Site of Delivery: _____

Pre-Delivery

Focus	Details			Date & Clarification, if necessary	Initials
Infectious Disease Contact	Referred to Dr. _____	Yes	No		
OB/GYN Contact	Dr: _____	Yes	No		
Birth Control*	Discuss postpartum options				
Pediatric Infectious Diseases Contact (medication for babies in complex cases)	Dr. _____				
Public Health Contact	HIV Prenatal Nurse Designate: 780-342-2322				
Contact / Support Person	Primary contact: _____ Other Community Resources:	Yes	No		
If Out of Region: PHN Contact	Name: _____ Phone: _____	Yes	No		
Mother Risk New or Old HIV	New: Patient aware of results Contact tracing done	Yes Yes	No No		
Ultrasound	Ultrasound booked Date: _____ Gestation: _____ Date: _____ Gestation: _____	Yes	No		
Focus Prenatal Screening	Details: Fasting glucose _____ Syphilis _____ Hepatitis A,B,C _____ Vaccines _____				
HIV Pocket Card Given	Pocket card with pregnancy details	Yes	No		
Prophylaxis for Mom	Is this required? (for PJP, MAC) Medications: (if yes)	Yes	No		
Antiretrovirals for Mom	Started: Meds:	Yes	No		
Other Medications Mother Is Taking	Name: Dose:				

* *At Covenant Health Group facilities, references to contraceptive practices, assisted fertilization and counseling options regarding the continuation of pregnancies must be balanced with the moral considerations and prohibitions presented in the Health Ethics Guide, the foundational ethical framework used in Catholic healthcare institutions, including Covenant. The principle of legitimate cooperation may apply in some instances. An ethics consult is recommended to help interpret specific cases where this applies.*

Focus	Details			Date & Clarification, if necessary	Initials
Info Package to Mom	Given to mother and reviewed with her. Date: _____ Advised Mom on: □ Cesarean section and HIV □ No breastfeeding: provision of formula for up to one year □ AZT® for baby, importance of AZT® Printed information given: _____				
Nutrition for Infant	Primary contact for formula: _____	Yes	No		
Hospital Caseroom	□ Relevant correspondence □ Client care sheet □ Database faxed one month prior to EDC	Yes	No		
Viral Loads During Pregnancy	VL _____ Date _____ VL _____ Date _____ Include the word "**pregnant**" on requisition.				
Pharmacy at Hospital of Delivery	AZT® Supply – Liaison Pharmacy RE: delivery, EDC, availability of medications for mom and baby	Yes	No		

LABOUR

Focus	Details			Date & Clarification, if necessary	Initials
HIV Viral Load	Viral load near the time of delivery _____ Date: _____	Yes	No		
Zidovudine (AZT®) Infusion Started	Date/Time: _____ Medication: _____			Reason if No:	
Other Antiretrovirals	List:	Yes	No		
Fetal Monitoring	Type:	Yes	No		
Invasive Procedure During Labour	Type:	Yes	No		
Delivery Type	□ Vaginal □ Elective cesarean section □ Emergency cesarean section				
PROM (greater than 4 hrs prior to delivery)	How long before delivery _____	Yes	No		
Pediatric Infectious Diseases Contacted	Dr. _____	Yes	No		

Post Delivery Support & Tracking

Focus	Details			Date & Clarification, if necessary	Initials
Neonatal zidovudine (PO/IV) First Dose	Date: _____ Time: _____ Other ARVs: _____				
Oral zidovudine (AZT®) Supply for Baby	6 week drug supply provided to mom prior to discharge. Date: _____	Yes	No		
Other Antiretrovirals	List:	Yes	No		
Oral Syringes	Given to mom with instructions how to clean.	Yes	No	Amount given:_____	
Beeper for infant Medications and Administration Times		Yes	No		
ID Pediatrician Follow-up	Initial follow-up appointment for baby arranged (2 weeks after delivery) with Pediatric Infectious Diseases at the UAH.	Yes	No	Date: _____ Dr.:_____	
Formula	Provided mom with supply at discharge.	Yes	No	Type of Formula:_____ Amount given:_____	
Postpartum Antiretrovirals for Mother	Mom to continue with her meds after delivery.	Yes	No	Has supply at discharge	
ID Follow-up for Mother	Book appointment for mother with her Adult Infectious Disease Specialist	Yes	No	Date/Time:_____ Physician: _____	
Birth Control Options	Given Depo-Provera® (or other) at discharge	Yes	No	If other: _____	
Antiretroviral Compliance for Baby	Mom contacted weekly for 6 weeks postnatal	Yes	No	End date for Infant meds: _____	
Tracking	Healthy Beginnings discharge form received	Yes	No		

Baby Destination

Focus	Details			Date & Clarification, if necessary	Initials
Destination	Home with mom Fostered Out Adopted Out Apprehended	Yes Yes Yes Yes	No No No No		

Social Issues

Focus	Details			Date & Clarification, if necessary	Initials
Infant Adopted / Fostered Out	□ In Edmonton Zone □ Outside of Edmonton Zone			Contact Person: _____	
Assistance Arranged for	□ Social Services □ Mental Health Support □ Drug Abuse Treatment □ Housing □ Food / Baby Formula □ Transportation □ Child Care □ Financial				
	□ Referral to another Public Health Program			Specify:	

COMMENTS

Date of Completion: _____

Nurse: _____

Appendix H

Important Phone Numbers

	Contact Information	Comments
Laboratory STAT HIV Request	Page virologist-on-call through University Hospital switchboard at 780-407-8822	Alternatively, call the 24 hour Microbiology number at 780-407-7121
Prenatal Testing Results	780-407-8667	Dedicated phone line for prenatal HIV test results; operates on a 24 hr basis. Results will be released to a nurse or physician caring for the patient.
Medical Officer of Health	780-342-0185 (during the day) 780-433-3940 (after hours)	
Adult Infectious Diseases	780-407-8822 UAH switchboard 780-735-4111 RAH switchboard	
Pediatric Infectious Diseases	780-248-5540 (during the day)	Call UAH switchboard to page on-call physician 780-407-8822
HIV Nurse (RAH site)	780-735-5340 Phone 780-735-4866 Fax	Only available during daytime hours. Secretary: 780-735-4811
Public Health, Prenatal HIV Nurse Designate	780-342-2322 Phone 780-425-2194 Fax	
Rexall Outpatient Pharmacy RAH site	780-735-5296 Phone 780-735-5258 Fax	Monday to Friday 0900-1700 hrs
Rexall Outpatient Pharmacy U of A site	780-407-6990 Phone 780-407-1090 Fax	Monday-Friday 0800-1800 hrs, Saturday 0800-1300 hrs

Appendix I

Neonatal Doses of Antiretrovirals for the Prevention of Mother to Child Transmission of HIV

Medication	Dose	How Supplied / Storage	Food Restrictions	Comments
zidovudine (Retrovir®) AZT, ZDV	**Perinatal Exposure:** **Start ZDV within less than 6 hours after birth and administer for 6 weeks.** **Greater than or equal to 35 weeks:** *PO AZT:* 4 mg/kg/dose PO q12h x 6 weeks **OR** *IV AZT:* 3 mg/kg/dose IV q12h x 6 weeks **30-34 weeks:** *PO AZT:* 2 mg/kg/dose PO q12h x 2 weeks, then 3 mg/kg/dose q12h until 6 weeks of age **OR** *IV AZT:* 1.5 mg/kg/dose IV q12h x 2 weeks, then 2.3 mg/kg/dose q12h until 6 weeks of age **less than 30 weeks:** *PO AZT:* 2 mg/kg/dose PO q12h x 4 weeks, then 3 mg/kg/dose q12h until 6 weeks of age **OR** *IV AZT:* 1.5 mg/kg/dose IV q12h x 4 weeks, then 2.3 mg/kg/dose q12h until 6 weeks of age	10 mg/mL strawberry syrup (240 mL bottle). Store at room temperature. 200 mg/20 mL vial intravenous	Take with or without food/feeds.	- If zidovudine upsets stomach, take after feeds. - Should not be administered with stavudine (d4T, Zerit®) due to poor antiretroviral effect.
Nevirapine (Viramune®) NVP	**Newborn Perinatal Prophylaxis:** Three-dose PO nevirapine: • Birth weight less than 1.5 kg: 2 mg**/kg per dose** (note: **dose per kg** for this weight) • Birth weight 1.5 to 2 kg: 8 mg **per dose** • Birth weight greater than 2 kg: 12 mg **per dose** **For all weights, 3 doses are given in the first week of life:** • 1st dose at birth (as soon as possible and no later than 6 hours after birth) • 2nd dose on day 2 (48 hours after the 1st dose) • 3rd dose on day 6 (96 hours after the 2nd dose)	10 mg/mL sweet flavored syrup (240 mL bottle). Store at room temperature. **Available through Special Access Program[1].**	May take with or without food/feeds.	- Do not increase dose if rash occurs within first 14 days. - A dose of 8 mg equals 0.8 mL of the syrup. - A dose of 12 mg equals 1.2 mL of the syrup.

Medication	Dose	How Supplied / Storage	Food Restrictions	Comments
lamivudine (3TC®)	**Neonatal/Infant Dose (infants less than 30 days):** 2 mg/kg/dose PO q12h **Pediatric Dose:** 4 mg/kg/dose PO q12h	10 mg/mL strawberry-banana oral liquid (240 mL bottle). Store at room temperature.	Take with or without food/feeds.	
nelfinavir (Viracept®)	• Birth weight less than 1.5 kg: ○ 50 mg/**kg per dose** PO every 12 hours (note: **dose per kg** for this weight) • Birth weight 1.5 to 2 kg: ○ 100 mg PO **per dose** every 12 hours • Birth weight 2.1 to 3 kg: ○ 150 mg PO **per dose** every 12 hours • Birth weight greater than 3 kg: ○ 200 mg PO **per dose** every 12 hours	250 mg PO tablet- requires crushing and mixing with sterile water	Best absorbed with food/feeds in the stomach. Once the medication is given, try to give the baby a regular feeding of formula.	- Crush a 250 mg tablet and mix in 5 mL (1 teaspoon) of sterile water (previously boiled and cooled water) to make a 50 mg/mL liquid. Mix well. Let sit for 5 to 10 minutes. Stir and give within 20 minutes. - Use a 5 mL syringe with 0.2 mL increments to measure out the prescribed dose. - A dose of 100 mg equals 2 mL of the liquid; a dose of 150 mg equals 3 mL of the liquid; a dose of 200 mg equals 4 mL of the liquid. - The liquid is stable for up to 6 hours in the refrigerator, but it is best to use as soon as possible after mixing the dose. - Make a new suspension for each dose (do not save the liquid from previous doses).
didanosine (Videx®) ddl	**Neonatal Dose (up to 4 months):** 50 mg/m^2/dose PO q12h	4 g pediatric powder for oral solution (final concentration of 10 mg/mL). Refrigerate for up to 30 days (shake well before using). **Available through Special Access Program**[1].	Take on an empty stomach (1 hour before feeds or 2 hours after). Do not give with fruit juices or acidic drinks, feeds or milk.	4 g bottle: Reconstituted with Alma Gel Antacid (DIN 00569801) (200 mg $MgOH_2$ + 200 mg $ALOH_3$) Add 400 mL of antacid in two, 200 mL portions, shaking the contents after each addition of 200 mL (see note).[2] Note: The admixture may be dispensed in flint-glass or plastic bottles. Combination of stavudine (d4T) and didanosine (ddl) is not recommended (unless benefits outweigh the risks) due to overlapping toxicities.

1.These drugs are available through a 'Special Access Program. The special access forms are available on the Health Canada website at (http://www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapf1_pasf1_e.html). Contact the inpatient or outpatient pharmacy for further assistance.
2.Maalox Extra Strength is discontinued from the market. Please note that the manufacturer instructions recommend the use of Maalox Extra Strength for Videx reconstitution. However since Maalox Extra Strength is no longer available, Alma Gel Antacid is a reasonable substitute (note specific strength and volume of this product differ from Maalox Extra Strength, therefore the instructions for reconstitution are different).

Appendix J

Intravenous Zidovudine (ZDV) Preparation and Administration Protocol

Recommended Supplies:

5 - Vials zidovudine 200 mg/20 mL (concentration 10 mg/mL)

1 - IV bag 500 mL (D5W, NS, D5-1/2S, LR and D5-LR)

To make a standard zidovudine concentration: 2 mg/mL

1. Remove 100 mL from 500 mL IV bag.
2. Withdraw contents of 5 zidovudine vials (100 mL). [5 x 20 mL per vial = 100 mL (= 1000 mg)]
3. Add the 100 mL of zidovudine to the IV bag to total 500 mL.

NOTE: This solution is stable for 8 hours at room temperature (or 24 hours if refrigerated). The maximum concentration of zidovudine is 4 mg/mL.

Dosage of zidovudine during labour:

Loading dose: 2 mg/kg* infused over 1 hour.
Continuous infusion: 1 mg /kg/ hour* continuous infusion until umbilical cord clamped.
For scheduled cesarean section, start the zidovudine 3 hours prior to surgery.

Zidovudine Dosing Table:*
***Only to be used for standard 2 mg/mL solution**
Round patient's weight to the nearest 2 kg

Wt (kg)	**LOADING DOSE** Set pump at this rate **FOR FIRST HOUR ONLY (mL/hour)**	**CONTINUOUS INFUSION** Set pump at this rate ***(after loading dose)*** (mL/hour)	**Wt (kg)**	**LOADING DOSE** Set pump at this rate **FOR FIRST HOUR ONLY** (mL/hour)	**CONTINUOUS INFUSION** Set pump at this rate ***(after loading dose)*** (mL/hour)
50	50	25	90	90	45
52	52	26	92	92	46
54	54	27	94	94	47
56	56	28	96	96	48
58	58	29	98	98	49
60	60	30	100	100	50
62	62	31	102	102	51
64	64	32	104	104	52
66	66	33	106	106	53
68	68	34	108	108	54
70	70	35	110	110	55
72	72	36	112	112	56
74	74	37	114	114	57
76	76	38	116	116	58
78	78	39	118	118	59
80	80	40	120	120	60
82	82	41	122	122	61
84	84	42	124	124	62
86	86	43	126	126	63
88	88	44	128	128	64

Zidovudine Compatibility:

Y-SITE:

Zidovudine is compatible with the following (usual administration concentrations for both drugs) in **D5W ONLY** (unless indicated):

acyclovir	co-trimoxazole	heparin	phenylephrine
allopurinol – mix in NS only	dexamethasone	imipenem-cilastatin	piperacillin
amifostine	dobutamine	linezolid	piperacillin-tazobactam
amikacin	docetaxel	lorazepam	potassium Cl
amphotericin B	dopamine	melphalan – mix in NS only	ranitidine
anidulafungin	erythromycin	metoclopramide	remifentanil – mix in NS or D5W
aztreonam	filgrastim (G-CSF)	morphine	sargramostim – mix in NS only
ceftazidime	fluconazole – both drugs undiluted	ondansetron – mix in NS or D5W	teniposide
ceftriaxone	fludarabine	oxytocin	thiotepa
cimetidine	gemcitabine – mix in NS only	paclitaxel	tobramycin
cisatracurium	gentamicin	pentamidine	vancomycin
clindamycin			vinorelbine – mix in NS only

INCOMPATIBILITY

meropenem

Zidovudine Compatibility Table adapted from reference 2 below (with permission):

Note: There is no compatability data on IV cefazolin and IV zidovudine. In the case of a cesarean section, IV zidovudine should be initiated 3 hours prior to surgery and IV cefazolin within 1 hour prior to surgery. It is recommended to clamp and flush the line with NS (the line infusing IV zidovudine), administer IV cefazolin via IV push, flush the line again with NS, and resume IV zidovudine immediately.

References (adapted from):

1) Oak Tree Children & Women's Health Centre of British Columbia
http://www.bcwomens.ca/NR/rdonlyres/F4FFE776-2CE2-4759-9C6C-DAB0CDCD5301/58319/IVzidovudine.pdf

2) Zidovudine Parenteral Monograph, version 4, July 12, 2011. Edmonton Zone/Covenant Health (Edmonton zone). Regional Parenteral Manual [manual on Alberta Health Services Intranet]. Edmonton, AB: Drug Information Centre, Pharmacy Services, Alberta Health Services - Edmonton; c1999–2014. Accessed from: http://insite.albertahealthservices.ca/7575.asp on March 3, 2014.

Appendix K

Alberta Health Services | Covenant Health

Pediatric Patient Education Sheet

ZIDOVUDINE

Other names: Retrovir®/AZT

What is zidovudine used for?

- Zidovudine may be given to babies after birth to help prevent the baby from getting HIV infection.

How do you give zidovudine to your child?

Instructions:

The dose of zidovudine liquid for your baby is _____mg (which is _____mL) given at the

following times: _____

Administration Notes: _____

Give before, during or after a feed

Give the medicine regularly until the stop date of: _____.

- Zidovudine is available as strawberry flavoured syrup (10 mg/mL). Each dose for a newborn is usually less than 2 mL.
- Zidovudine should be given at the same times each day as in the above schedule.
- Always measure each dose with specially marked oral syringe with 0.1 mL increments provided with the medication. For example: a dose of 11 mg equals 1.1 mL of syrup. The syringe should be washed with water and thoroughly rinsed with previously boiled water after each use.
- Zidovudine may be given before, after or during a feed. To give the medicine, gently place the oral syringe in the baby's mouth just inside the cheek and give 4 or 5 gentle pushes on the plunger of the syringe. Allow the baby to swallow the liquid between pushes on the plunger to ensure that the baby does not gag or choke. Ensure that the baby receives the full dose of zidovudine.
- It is not a good idea to mix zidovudine with the baby's formula. The reason is that if the baby does not drink all of the formula, he/she will not get the full dose.
- Store the medication at room temperature. *Do not store in your bathroom as heat and moisture may cause the medicine to lose its effectiveness.*
- ***KEEP THIS AND ANY OTHER MEDICATIONS OUT OF SIGHT AND OUT OF REACH FROM CHILDREN.***

What special instructions do you need to know?

- If you forget to give your baby his/her dose of zidovudine, give it to him/her as soon as possible. However if it is time for your baby's next dose, do not double the dose; just carry on with the regular schedule.
- If your baby vomits within 15 minutes of giving the dose, give another dose if possible. If it is more than 15 minutes after the dose, do not give another dose and wait until the next regular dose.

Are there side effects from taking zidovudine?

- As with any medication, side effects can rarely occur.
- Zidovudine can interact with other drugs. It is important that your physician or pharmacist know about other prescription and non-prescription medications your baby is taking. Acetaminophen (Atasol®, Tempra®, and Tylenol®) may be given safely with zidovudine.

When should you call your child's doctor?

- If you think your baby is having problems with the medications, discuss this with your baby's doctor (Pediatric Infectious Diseases doctor) or the HIV program pharmacist. Do **not** stop a medication or make changes to your baby's treatment unless recommended by your doctor.

What can you do to help make sure your child's medication works properly?

- It is very important not to miss any doses of this medicine. If you are having trouble remembering to give this medicine, you can set an alarm or ask your pharmacist for a "beeper' to remind you.

NOTES:

Syringes:

- Use each syringe for 1 day then discard. Wash with water and rinse the syringe between uses with previously boiled water 2-3 times until syringe is clean and no longer sticky. If you run out of syringes, please contact Public Health, Prenatal HIV Nurse Designate for more syringes at 780-342-2322.

Doctor's Appointment for the Baby:

- Your baby will need to see a Pediatric Infectious Diseases doctor at the University Hospital at **2 weeks** of age to review medications and to make sure the right tests are done on your baby. If you do not already have an appointment, please talk to your public health nurse or call the Pediatric Infectious Diseases secretary at 780-248-5540. It is very important to keep all follow-up medical appointments for your baby.

References:

Product Monograph. Retrovir® (AZT, zidovudine). Mississauga, ON: ViiV Healthcare Shire Canada, June 2010.

Appendix L

Pediatric Patient Education Sheet

NEVIRAPINE

Other names: Viramune®/NVP

What is nevirapine used for?

- Nevirapine may be given to babies after birth to help prevent the baby from getting HIV infection.

How do you give nevirapine to your child?

Instructions:

The dose of nevirapine liquid for your baby is _____mg (which is _____mL) given on the following dates and at the following times:

_____

Administration Notes: _____

Give before, during or after a feed

Give the medicine regularly until the stop date of: _____.

- Nevirapine is available through the Health Canada's Special Access Program. Nevirapine is available as sweet flavoured syrup (10 mg/mL). Each dose for a newborn is usually less than 2 mL.
- Nevirapine should be given as in the above schedule.
- Always measure each dose with specially marked oral syringe with 0.1 mL increments provided with the medication. For example: a dose of 8 mg equals 0.8 mL of syrup. The syringe should be washed with water and thoroughly rinsed with previously boiled water after each use.
- Nevirapine may be given before, after or during a feed. To give the medicine, gently place the oral syringe in the baby's mouth just inside the cheek and give 4 or 5 gentle pushes on the plunger of the syringe. Allow the baby to swallow the liquid between pushes on the plunger to ensure that the baby does not gag or choke. Ensure that the baby receives the full dose of nevirapine.
- It is not a good idea to mix nevirapine with the baby's formula. The reason is that if the baby does not drink all of the formula, he/she will not get the full dose.
- Store the medication at room temperature. *Do not store in your bathroom as heat and moisture may cause the medicine to lose its effectiveness.*
- ***KEEP THIS AND ANY OTHER MEDICATIONS OUT OF SIGHT AND OUT OF REACH FROM CHILDREN.***

What special instructions do you need to know?

- If you forget to give your baby his/her dose of nevirapine, give it to him/her as soon as possible. Do not double the dose of medication.
- If your baby vomits within 15-30 minutes of giving the dose, give another dose if possible. If it is more than 15-30 minutes after the dose, contact your health care provider for advice on when to give the next dose (since the doses are only given on specific days over a period of a week).

Are there side effects from taking nevirapine?

- As with any medication, side effects can rarely occur.
- Nevirapine can interact with other drugs. It is important that your physician or pharmacist know about other prescription and non-prescription medications your baby is taking. Acetaminophen (Atasol®, Tempra®, and Tylenol®) may be given safely with nevirapine.

When should you call your child's doctor?

- If you think your baby is having problems with the medications, discuss this with your baby's doctor (Pediatric Infectious Diseases doctor) or the HIV program pharmacist. Do **not** stop a medication or make changes to your baby's treatment unless recommended by your doctor.

What can you do to help make sure your child's medication works properly?

- It is very important not to miss any doses of this medicine. If you are having trouble remembering to give this medicine, you can set an alarm or ask your pharmacist for a "beeper' to remind you.

NOTES:

Syringes:

- Use each syringe for 1 dose then discard. If you run out of syringes, please contact Public Health, Prenatal HIV Nurse Designate for more syringes at 780-342-2322.

Doctor's Appointment for the Baby:

- Your baby will need to see a Pediatric Infectious Diseases doctor at the University Hospital at **2 weeks** of age to review medications and to make sure the right tests are done on your baby. If you do not already have an appointment, please talk to your public health nurse or call the Pediatric Infectious Diseases secretary at 780-248-5540. It is very important to keep all follow-up medical appointments for your baby.

References: Product Monograph. Viramune® (nevirapine). Ridgefield, CT: Boehringer Ingelheim, November 2011.

Appendix M

Pediatric Patient Education Sheet

LAMIVUDINE

Other names: 3TC®

What is lamivudine used for?

- Lamivudine is used to help prevent the baby from getting HIV infection after the baby is born.

How do you give lamivudine to your child?

Instructions:

The dose of lamivudine liquid for your baby is _____mg (which is _____mL) given at the following times:_____

Administration Notes:_____

Give before, during or after a feed

Give the medicine regularly until the stop date of: _____.

- Lamivudine is available as a strawberry-banana flavored solution (10 mg/ml). Give lamivudine before, during or after a feed.
- Lamivudine should be given at the same times each day as in the above schedule.
- Always measure each dose with specially marked oral syringe with 0.1 mL increments provided with the medication. For example, a dose of 7 mg equals 0.7 mL of the solution. The syringe should be washed with water and thoroughly rinsed with previously boiled water after each use.
- To give the medicine, gently place the oral syringe in the baby's mouth just inside the cheek and give 4 or 5 gentle pushes on the plunger of the syringe. Allow the baby to swallow the liquid between pushes on the plunger to ensure that the baby does not gag or choke. Ensure that the baby receives the full dose of lamivudine.
- *It is not a good idea to mix lamivudine with the baby's formula. The reason is that if the baby does not drink all of the formula, he/she will not get the full dose.*
- Store the medication at room temperature. Do not store in your bathroom as heat and moisture may cause the medicine to lose its effectiveness.
- ***KEEP THIS AND ANY OTHER MEDICATIONS OUT OF SIGHT AND OUT OF REACH FROM CHILDREN.***

What special instructions do you need to know?

- If you forget to give your baby his/her dose of lamivudine, give it to him/her as soon as possible. However if it is time for your baby's next dose, do not double the dose; just carry on with the regular schedule.
- If your baby vomits within 15 minutes of giving the dose, give another dose if possible. If it is more than 15 minutes after the dose, do not give another dose and wait until the next regular dose.

Are there side effects from taking lamivudine?

- As with any medication, side effects can rarely occur.
- Lamivudine can interact with other drugs. It is important that your physician or pharmacist know about other prescription and non-prescription medications your baby is taking. Acetaminophen (Atasol®, Tempra®, and Tylenol®) may be given safely with lamivudine.

When should you call your child's doctor?

- If you think your baby is having problems with the medications, discuss with your baby's doctor (Pediatric Infectious Diseases doctor) or the HIV program pharmacist. Do not stop a medication or make changes to your baby's treatment unless recommended by your doctor.

What can you do to help make sure your child's medication works properly?

- It is very important not to miss any doses of this medication. If you are having trouble remembering to give this medication, you can set an alarm or ask your pharmacist for a "beeper' to remind you.

NOTES:

Syringes:

- Use each syringe for 1 day then discard. Wash syringe with water and rinse the syringe between uses with previously boiled water 2-3 times until syringe is clean and no longer sticky. If you run out of syringes, please notify a Public Health, Prenatal HIV Nurse Designate at 780-342-2322 so we can give you more.

Doctor's Appointment for the Baby:

- Your baby will need to see a Pediatric Infectious Diseases doctor at the University Hospital when baby is **2 weeks** old to review medications and to make sure the right tests are done on your baby. If you do not already have an appointment, please talk to your public health nurse or call the Pediatric Infectious Diseases secretary at 780-248-5540. It is very important to keep all follow-up medical appointments for your baby.

References:

Product Monograph. 3TC® (lamivudine). Mississauga, ON: ViiV Healthcare Shire Canada, Aug 2010.

Appendix N

Pediatric Patient Education Sheet

NELFINAVIR

Other names: Viracept®/NFV

What is nelfinavir used for?

- Nelfinavir may be given to babies after birth to help prevent the baby from getting HIV infection.

How do you give nelfinavir to your child?

Instructions:

The dose of nelfinavir liquid for your baby is _____mg (which is _____mL) given at the following times:_____

Administration Notes:_____

Give before, during or after a feed

Give the medicine regularly until the stop date of: _____.

- Nelfinavir is available as a tablet that requires additional preparation as outlined below.
- Crush a 250 mg tablet and mix in 5 mL (1 teaspoon) of sterile water (previously boiled and cooled water) to make a 50 mg/mL liquid. Mix well. Let sit for 5 to 10 minutes. Stir and give within 20 minutes.
- Use a 5 mL syringe with 0.2 mL increments to measure out the prescribed dose. For example, a dose of 200 mg equals 4 mL of the liquid.
- To give the medicine, gently place the oral syringe in the baby's mouth just inside the cheek and give 4 or 5 gentle pushes on the plunger of the syringe. Allow the baby to swallow the liquid between pushes on the plunger to ensure that the baby does not gag or choke. Ensure that the baby receives the full dose of nelfinavir.
- Once the medication is given, try to give the baby a regular feeding of formula after. **Nelfinavir works best when there is formula in the baby's stomach.**
- It is not a good idea to mix nelfinavir with the baby's formula. The reason is that if the baby does not drink all of the formula, he/she will not get the full dose.
- The liquid is stable for up to 6 hours in the refrigerator, but it is best to use as soon as possible after mixing the dose.
- Make a new suspension for each dose (do not save the liquid from previous doses).
- *Store the tablets at room temperature. Do not store in your bathroom as heat and moisture may cause the medicine to lose its effectiveness.*
- ***KEEP THIS AND ANY OTHER MEDICATIONS OUT OF SIGHT AND OUT OF REACH FROM CHILDREN.***

What special instructions do you need to know?

- If you forget to give your baby his/her dose of nelfinavir, give it to him/her as soon as possible. However if it is time for your child's next dose, do not double the dose; just carry on with the regular schedule.
- If your baby vomits within 15 minutes of giving the dose, give another dose if possible. If it is after 15 minutes, do not give another dose and wait until the next regular dose.

Are there side effects from taking nelfinavir?

- As with any medication, side effects can rarely occur.
- Nelfinavir can interact with other drugs. It is important that your physician or pharmacist know about other prescription and non-prescription medications your child is taken. Acetaminophen (Atasol®, Tempra®, and Tylenol®) may be given safely with nelfinavir.

When should you call your child's doctor?

- If you think your baby is having problems with the medications, discuss this with your baby's doctor (Pediatric Infectious Diseases doctor) or the HIV program pharmacist. Do not stop a medication or make changes to your baby's treatment unless recommended by your doctor.

What can you do to help make sure your child's medication works properly?

- It is very important not to miss any doses of this medication. If you are having trouble remembering to give this medication, you can set an alarm or ask your pharmacist for a "beeper' to remind you.

NOTES:

Syringes:

- Use each syringe for 1 day, then discard. Wash with water and rinse the syringe with previously boiled water 2-3 times until syringe is clean and no longer sticky. If you run out of syringes, please contact Public Health, Prenatal HIV Nurse Designate for more syringes at 780-342-2322.

Doctor's Appointment for the Baby:

- Your baby will need to see a Pediatric Infectious Diseases doctor at the University Hospital at **2 weeks** of age to review medications and to make sure the right tests are done on your baby. If you do not already have an appointment, please talk to your public health nurse or call the Pediatric Infectious Diseases secretary at 780-248-5540. It is very important to keep all follow-up medical appointments for your baby.

References:

Product Monograph. Viracept® (nelfinavir). Kirkland, QC: Pfizer Canada LTD, July 2011.
Data on file. Viracept® (nelfinavir). Kirkland, QC: Pfizer Canada LTD.

Appendix O

Pediatric Patient Education Sheet

DIDANOSINE

Other names: Videx®/ ddI

What is didanosine used for?

- Didanosine may be given to babies after birth to help prevent the baby from getting HIV infection.

How do you give didanosine to your child?

Instructions:

The dose of didanosine liquid for your baby is _____mg (which is _____mL) given at the following times: _____

Administration Notes: _____

Give 1 hour before or 2 hours after feeds.

Give the medicine regularly until the stop date of: _____

- Didanosine works best when the baby's stomach is empty. Try to administer the dose either 1 hour before feeds or 2 hours after feeds. Do not give didanosine at the same time as other medicines.
- Didanosine should be given at the same times each day as in the above schedule.
- Didanosine is mixed with an antacid in the pharmacy to make an oral solution (final concentration is 10 mg/mL). The solution should be stored in the refrigerator and is stable for 30 days. Discard unused portions after 30 days.
- **Shake** the bottle well before measuring out the dose.
- Always measure each dose with a specially marked oral syringe with 0.1mL increments provided with the medication. For example: a dose of 8mg equals 0.8 mL of suspension. The syringe should be washed with water and thoroughly rinsed with previously boiled water after each use.
- To give the medicine, gently place the oral syringe in the baby's mouth just inside the cheek and give 4 or 5 gentle pushes on the plunger of the syringe. Allow the baby to swallow the liquid between pushes on the plunger to ensure that the baby does not gag or choke. Ensure that the baby receives the full dose of didanosine.
- It is not a good idea to mix didanosine with the baby's formula. The reason is that if the baby does not drink all of the formula, he/she will not get the full dose.
- ***KEEP THIS AND ANY OTHER MEDICATIONS OUT OF SIGHT AND OUT OF REACH FROM CHILDREN.***

What special instructions do you need to know?

- If you forget to give your baby his/her dose of didanosine, give it to him/her as soon as possible. However if it is time for your baby's next dose, do not double the dose; just carry on with the regular schedule.
- If your baby vomits within 15 minutes of giving the dose, give another dose if possible. If it is more than 15 minutes after the dose, do not give another dose and wait until the next regular dose.

Are there side effects from taking didanosine?

- As with any medication, side effects can rarely occur.
- Didanosine can interact with other drugs. It is important that your physician or pharmacist know about other prescription and non-prescription medications your baby is taking. Acetaminophen (Atasol®, Tempra®, and Tylenol®) may be given safely with didanosine.

When should you call your child's doctor?

- If you think your baby is having problems with the medications, discuss with your baby's doctor (Pediatric Infectious Diseases doctor) or the HIV program pharmacist. Do not stop a medication or make changes to your baby's treatment unless recommended by your doctor.

What can you do to help make sure your child's medication works properly?

- It is very important not to miss any doses of this medication. If you are having trouble remembering to give this medication, you can set an alarm or ask your pharmacist for a "beeper' to remind you.

NOTES:

Syringes:

- Use each syringe for 1 day, then discard. Wash syringe with water and rinse the syringe between uses with previously boiled water 2-3 times until syringe is clean and no longer sticky. If you run out of syringes, please notify Public Health, Prenatal HIV Nurse Designate at 780-342-2322 so we can give you more.

Doctor's Appointment for the Baby:

- Your baby will need to see a Pediatric Infectious Diseases doctor at the University Hospital when baby is **2 weeks** old to review medications and make sure the right tests are done on your baby. If you do not already have an appointment, please talk to your public health nurse or call the Pediatric Infectious Diseases secretary at 780-248-5540. It is very important to keep all follow-up medical appointments for your baby.

References:

Product Monograph. Videx® (didanosine). Princeton, NJ: Bristol-Myers Squibb, November 2011.

References

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 HIV-1 Transmission in the United States. September 14, 2011: pp 1-207. Accessed at: http://aidsinfo.nih.gov

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 HIV-1 Transmission in the United States. July 31, 2012: pp i- J3. Accessed at: http://aidsinfo.nih.gov

BC Women's Hospital and Health Centre. Clinical Guidelines/HIV Protocols, 2010. Accessed at: http://www.bcwomens.ca/Services/HealthServices/OakTreeClinic/default.htm

CDC. Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health Care Settings. MMWR 2006; 55(RR14); 1-17

AIDS info. HIV and Pregnancy. Health Information for Patients. December 2010. Accessed at: http://aidsinfo.nih.gov

Canadian HIV Trials Network Working Group on Vertical HIV Transmission. Canadian consensus guidelines for the management of pregnancy, labour and delivery and for postpartum care in HIV-positive pregnant women and their offspring (summary of 2002) guidelines. Commentary. CMAJ 2003; 168(13): 1671-74.

Nizova NN, Posokhova SP. Preventing Mother-to-Child Transmission of HIV: A Practical Guide to the Prevention and Treatment of Sexually Transmitted Infections. 2nd edition. American International Health Alliance, Feb 2005.

Mirochnick M, Nielsen-Saines K, Pilotto JH, et al. Nelfinavir and lamivudine pharmacokinetics during the first two weeks of life. Pediatr Infect Dis J 2011; 30:769-772.