

CHAPTER 5

PREVENTION OF PERINATAL HIV TRANSMISSION

II. SCIENTIFIC DATA REGARDING ANTIRETROVIRAL PROPHYLAXIS PREVENTING PERINATAL TRANSMISSION

A. Studies of Zidovudine Alone

See Table 1.

TABLE 1 RESULTS OF OBSERVATIONAL STUDY OF 939 HIV-EXPOSED INFANTS IN NEW YORK STATE			
Timing of Prophylaxis Initiation	Number Born	Number Infected	Percent HIV Infected
Prenatal	423	26	6.1
Intrapartum	50	5	10.0
Before 48 hours postpartum	86	8	9.3
After 48 hours postpartum	38	7	18.4
No therapy	342	91	26.1

VIII. HIV TESTING OF PREGNANT WOMEN AND NEWBORNS IN NEW YORK STATE

RECOMMENDATIONS:

New York State regulations require HIV counseling with a clinical recommendation to test in all regulated prenatal care settings; NYSDOH recommends this as a standard of care in all other prenatal settings.

In New York State, HIV counseling and consented expedited testing are required if a woman presents in labor with no documented HIV test result from her current pregnancy and is not known to be HIV-infected. If the mother declines testing during labor, the infant should be tested immediately after birth. In this setting, consent for testing the newborn is not required. *HIV test results must be returned as soon as possible and no later than 48 hours after the specimen is obtained* (see Appendix XII).

The meaning of a positive preliminary test result should be discussed with the mother, and based on this discussion, the mother and the physician should decide whether to initiate ARV prophylaxis and whether to advise against breastfeeding.

ARV prophylaxis should be initiated as soon as possible during labor or after birth. It is most beneficial prior to birth or within 12 hours after birth and is unlikely to be beneficial if initiated beyond 48 hours after birth (for specific prophylaxis regimens, see Section XIV: *Labor and Newborn Management in the Absence of Antenatal Antiretroviral Treatment*).

A confirmatory Western blot assay should be performed as soon as possible after a positive preliminary expedited HIV test result.

IX. PRECONCEPTIONAL COUNSELING FOR HIV-INFECTED WOMEN

RECOMMENDATION:

Clinicians should discuss pregnancy planning issues with all HIV-infected women of childbearing age. This should include both a discussion of barrier methods to prevent transmission of HIV and sexually transmitted diseases and information on how to optimize a woman's chances of having a healthy, HIV-uninfected infant should she wish to become pregnant.

X. MONITORING OF HIV-INFECTED WOMEN DURING PREGNANCY

RECOMMENDATIONS:

The monitoring of pregnant HIV-infected women should be similar, if not more attentive, than that for other HIV-infected persons (see Chapter 1: *Antiretroviral Therapy for Adults*).

The provider should assess each HIV-infected pregnant woman early in pregnancy. This assessment should include a classification of clinical, immunologic, and virologic status as well as her support system and her capacity to adhere to medications.

Serum chemistries and complete blood counts should be performed at least every 3 to 4 months, although many experts perform these assays every 4 to 6 weeks, to screen for possible ARV toxicities.

Viral load assessments should be performed at least once a trimester, within 4 weeks after starting or changing ARV therapy. A viral load test should be performed at approximately 33 to 35 weeks' gestation to ensure that the most up-to-date information is available for consideration of an elective cesarean section.

Immunologic assessment should be performed every 3 months. Prophylaxis for opportunistic infections should be recommended at the same CD4 cell levels as for non-pregnant adults.

Pneumococcal and influenza vaccines should be given as recommended in non-pregnant adults.

XI. ANTIRETROVIRAL MANAGEMENT FOR PREGNANT WOMEN

RECOMMENDATIONS:

Clinicians should discuss with all patients the use of ARV agents with the dual purposes of preventing mother-to-child transmission and optimizing maternal health. This should include a discussion of the benefits and risks of ARV treatments to both mother and fetus. The provider should be non-coercive and culturally sensitive and should use language and terms that the patient can understand.

The woman should make her final decision about ARV therapy, including which regimen to take, in consultation with an HIV Specialist.

If a woman decides to refuse any level of ARV therapy or care, her provider should not deny her any other aspects of care. The provider should continue to recommend ARV therapy at subsequent visits and should discuss possible barriers to taking it.

The provider should stress the importance of adherence to a treatment regimen. Adherence to therapy should be encouraged and monitored at all antepartum and postpartum visits.

Efavirenz and hydroxyurea should be avoided in pregnant women.

The combination of didanosine and stavudine should be avoided in pregnant women if another alternative is feasible.

Intravenous zidovudine during labor should be strongly recommended for all HIV-infected pregnant women, regardless of which antenatal regimen they received.

XII. SPECIFIC ANTIRETROVIRAL ISSUES FOR AN ANTIRETROVIRAL-NAIVE PREGNANT WOMAN

A. Women With Viral Loads >1,000 Copies/mL

RECOMMENDATIONS:

If a woman's viral load is >1,000 copies/mL, the provider should recommend a HAART regimen that includes the three-part zidovudine regimen (see Appendices IX and X).

If a woman chooses not to receive HAART, she should be offered, at a minimum, the three-part zidovudine regimen (see Appendix X).

The provider should recommend that most women who begin ARV therapy during pregnancy start after the first trimester. For women with severe clinical, immunologic, or virologic disease, the urgent need for viral suppression may outweigh the risk of fetal toxicity during the first trimester.

B. Women With Viral Loads <1,000 Copies/mL

RECOMMENDATIONS:

If a woman's viral load is <1,000 copies/mL, the provider should recommend at least the three-part zidovudine regimen (see Appendices IX and X).

The provider should discuss both the increase in potential toxicities and the slightly decreased risk of transmission for women receiving HAART despite a viral load <1,000 copies/mL. The provider should discuss the benefits and risks of HAART for women with viral loads <1,000 copies/mL without making a recommendation.

If a woman with a viral load <1,000 copies/mL strongly desires to receive HAART, the provider should make it available to her.

The provider should recommend that women with a viral load <1,000 copies/mL who begin ARV therapy during pregnancy start after the first trimester.

XIII. SPECIFIC ANTIRETROVIRAL THERAPY ISSUES FOR ANTIRETROVIRAL-EXPERIENCED PREGNANT WOMEN

RECOMMENDATIONS:

Providers should give women the option of continuing or discontinuing their ARV therapy during the first trimester. This decision will involve consideration of its potential effectiveness in suppressing viral load, the tolerability of the regimen, and the potential for toxicity during this period of organogenesis.

For women who choose to temporarily discontinue their regimen, all drugs should be discontinued and then restarted simultaneously.

Providers should recommend alternative regimens for women receiving efavirenz, hydroxyurea, or combination didanosine/stavudine.

Providers should discuss and stress the importance of adherence with all pregnant women receiving ARV therapy.

Resistance testing should be performed for all women who have detectable viral loads despite adhering to HAART to help determine the most suitable regimen.

Providers should offer alternative regimens for all women who are adhering to ARV therapy but who do not have undetectable levels of virus. Unless contraindicated, these new regimens should contain zidovudine. Regardless of the woman's antenatal regimen, intravenous zidovudine should be recommended during the intrapartum period.

XIV. MODE OF DELIVERY

RECOMMENDATIONS:

The provider should discuss the risks and benefits of a scheduled cesarean section as opposed to a vaginal delivery with each pregnant woman.

This discussion should include the potential increase in morbidity of cesarean section for both the woman and infant contrasted with a lower rate of transmission of HIV with scheduled cesarean section.

The provider should respect a woman's autonomy to decide which mode of delivery is best for her.

The provider should explain that the anticipated benefit from a cesarean section is dependent on the risk of HIV transmission; when other factors, such as viral suppression and ARV prophylaxis, are optimized, the benefit from a cesarean section is less.

The provider should discuss the benefits and risks of cesarean section with each woman. To help the woman make the most informed decision, the provider should inform her about rates of transmission among women with viral load levels similar to hers and among women receiving the ARV regimen that she is receiving.

Scheduled cesarean section before onset of labor or ruptured membranes is recommended for women with no antenatal ARV therapy or with a viral load >1,000 copies/mL at the time of delivery.

If a woman chooses cesarean section, it should be performed at 38 weeks' gestation. The woman should receive prenatal ARV medications for as long as possible until the surgery and should receive at least 3 hours of intravenous zidovudine prior to the surgery. The newborn should receive one of the ARV regimens listed in Section XV:

Labor and Newborn Management in the Absence of Antenatal Antiretroviral Treatment.

The benefit of cesarean section after onset of labor is unknown. Women in whom labor is rapidly progressing should be allowed to deliver vaginally. Rupture of membranes should be delayed as long as possible. When a provider anticipates a long period of labor and/or possible prolonged

rupture of membranes, the clinician and patient should weigh the risks of cesarean section against the benefit of reducing duration of rupture of membranes for women already in labor.

XV. LABOR AND NEWBORN MANAGEMENT IN THE ABSENCE OF ANTENATAL ANTIRETROVIRAL TREATMENT

RECOMMENDATION:

For women who have received no antenatal ARV therapy, options for prevention of transmission include the following (see Appendix XI):

- 1) intrapartum intravenous zidovudine followed by 6 weeks of zidovudine to the newborn; or
- 2) single-dose nevirapine at the onset of labor followed by a single dose of nevirapine to the newborn at 48 hours; or
- 3) oral zidovudine/lamivudine during labor followed by 1 week of oral zidovudine to the newborn; or
- 4) the two-dose nevirapine regimen at the onset of labor combined with intrapartum intravenous zidovudine and 6 weeks of zidovudine to the newborn.

XVI. ANTIRETROVIRAL PROPHYLAXIS FOR HIV-EXPOSED INFANTS

RECOMMENDATIONS:

If the mother has not received ARV therapy during pregnancy or labor, 6 weeks of zidovudine for the newborn is still recommended. In such situations, zidovudine should be started immediately after birth or as soon as the child is identified as HIV-exposed. In this circumstance, clinicians may give a single dose of nevirapine to the newborn as soon as possible after birth in addition to the 6-week newborn zidovudine regimen; however, no data yet exist demonstrating the benefits of this approach.

When a mother has not received any antenatal treatment but has received intrapartum treatment, the newborn should receive the same ARV regimen that was given to the mother. Options 1-4 are in Section XV and Appendix XI.

When a mother has received antenatal ARV, the newborn should be given at least the 6-week course of zidovudine.

The efficacy and safety of combining the zidovudine/lamivudine and nevirapine regimens or of giving HAART to newborns to prevent transmission have not been studied. Such regimens should be considered with extreme caution and in consultation with a pediatric HIV Specialist.

Premature infants and newborns unable to tolerate oral medication will require dose modification in conjunction with a pediatric HIV Specialist.

XVII. POST-PARTUM MANAGEMENT FOR THE MOTHER AND CHILD

RECOMMENDATIONS:

Proper ARV management requires continuity of care after the mother has delivered and a home environment conducive to giving medication and close medical follow-up. Referrals for case management, visiting nursing, and other services should be made as needed.

The clinician should ensure that a woman's records, in particular her ARV medication history, are transferred both to her primary care doctor once she is no longer pregnant and to the baby's pediatric primary and pediatric HIV Specialist.

An appointment with a pediatric HIV Specialist should be made before the infant is discharged from the nursery. Precautions to protect the confidentiality of patient information should be ensured.

A woman should be examined by her provider at approximately 2 weeks post-partum.

The provider should ensure that both mother and baby receive an adequate supply of ARV medication to continue the regimen through their post-partum and pediatric visits.

A woman may choose to continue or discontinue ARV medications after she has delivered. This decision is hers and should be made in concert with her primary care provider. The provider should make recommendations that are consistent with the guidelines in Chapter 1: *Antiretroviral Therapy for Adults*.

Breastfeeding by HIV-infected women is not recommended in the United States; if the infant has been breastfeeding, the mother should be counseled to discontinue.

Although anatomical abnormalities have not been reported to date, all infants exposed to ARV agents *in utero* should be examined for congenital abnormalities. If congenital abnormalities are found, they should be reported to the New York State Congenital Malformations Registry.

XVIII. PEDIATRIC FOLLOW-UP

RECOMMENDATIONS:

For newborns exposed to zidovudine, a complete blood count should be obtained at birth and at the completion of the 6-week course of therapy. Some clinicians recommend an additional monitoring visit at 3 to 4 weeks of life to assess the need for dose interruption or modification based on the amount of weight gained by the infant.

Routine evaluations should be performed for the early diagnosis of newborn HIV infection. HIV DNA PCR or HIV cultures are approved diagnostic tests for HIV infection in newborns. Plasma HIV RNA PCR should not be used as the sole diagnostic assay.

The timing of the first diagnostic test may vary; some clinicians recommend PCR testing as soon as possible after birth, while others may wait 2 or 4 weeks before testing.

For initial HIV testing, clinicians may either use the NYSDOH's Wadsworth Center in Albany, which provides testing at no cost (telephone no.: 518-474-2160) or submit documentation of HIV diagnostic test results from a laboratory with an appropriate New York State permit.

HIV-infected infants should receive comprehensive medical and psychosocial care in accordance with the updated NYSDOH/AI guidelines.⁹¹ Consultation with an HIV Specialist is strongly recommended.

ARV prophylaxis should be discontinued once the diagnosis of HIV infection has been established. An ARV treatment regimen should be initiated in consultation with a pediatric HIV Specialist (see Chapter 2: *Pediatric Antiretroviral Therapy*).

At 4 to 6 weeks of age, prophylaxis to prevent *Pneumocystis carinii* pneumonia should be initiated for HIV-exposed as well as HIV-infected infants.

Clinicians need to develop confidential systems to track and, if necessary, contact ARV-exposed, HIV-uninfected individuals if long-term toxicities are suspected or identified.

The NYSDOH is developing methods to look at long-term follow-up of ARV-exposed infants.

Clinicians should emphasize the need for the child's guardian to share responsibility for transmitting the child's history, including the history of his/her ARV exposure, to future primary care providers.

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APPENDIX II

CHARACTERISTICS OF ANTIRETROVIRAL DRUGS

The tables in these appendices are modified from tables in *Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and Adolescents* (2001) produced by The Department of Health and Human Services and Henry J. Kaiser Family Foundation, and *Public Health Service Task Force 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* produced by The Perinatal HIV Guidelines Working Group.

TABLE II-1
ZIDOVUDINE (AZT, ZDV)

Trade Name	Retrovir
Classification	Nucleoside reverse transcriptase inhibitor
Form	100-mg capsules 300-mg tablets 10-mg/mL IV solution 10-mg/mL oral solution
Dosing Recommendations	200 mg tid or 300 mg bid or with 3TC as Combivir†, 1 bid or with abacavir and 3TC as Trizivir‡, 1 bid
Food Effect	Take without regard to meals.
Oral Bioavailability	60%
Serum Half-life	1.1 hour
Intracellular Half-life	3 hours
Elimination	Metabolized to AZT glucuronide (GAZT) Renal excretion of GAZT
Adverse Events	Bone marrow suppression: Anemia and/or neutropenia Subjective complaints: GI intolerance, headache, insomnia, asthenia Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity.
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Yes (human, 0.85)
Long-Term Animal Carcinogenicity Studies	Positive (rodent, noninvasive vaginal epithelial tumors)
Animal Teratogen Studies	Positive (rodent-near lethal dose)
Black Box Warnings	Zidovudine may be associated with hematologic toxicities, including granulocytopenia and severe anemia, particularly in advanced HIV patients. Prolonged zidovudine use has been associated with symptomatic myopathy. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of antiretroviral nucleoside analogues alone or in combination.

† Each Combivir tablet contains 300 mg ZDV and 150 mg 3TC.

‡ Each Trizivir tablet contains 300 mg ZDV, 150 mg 3TC, and 300 mg abacavir.

TABLE II-2
DIDANOSINE (ddI)

Trade Name	Videx
Classification	Nucleoside reverse transcriptase inhibitor
Form	25-, 50-, 100-, 150-, 200*-mg chewable/dispersible buffered tablets 100-, 167-, 250-mg buffered powder for oral solution 125-, 200-, 250-, 400-mg enteric coated (EC) capsules
Dosing Recommendation	>60 kg: 200 mg bid (buffered tablets), 250 mg bid (buffered powder) or 400 mg qd† (buffered Tablets or EC capsules) <60 kg: 125 mg bid (buffered tablets), 167 mg bid (buffered powder), or 250 mg qd† (buffered tablets or EC capsules)
Food Effect	Levels down 55% Take 1/2 hour before or 2 hours after meal.
Oral Bioavailability	30-40%
Serum Half-life	1.6 hour
Intracellular Half-life	25-40 hours
Elimination	Renal excretion 50%
Adverse Events	Pancreatitis Peripheral neuropathy Nausea; diarrhea Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity.
FDA Pregnancy Category	B
Placental Passage (Newborn:Mother Drug Ratio)	Yes (human, 0.5)
Long-Term Animal Carcinogenicity Studies	Negative (no tumors, lifetime rodent study)
Animal Teratogen Studies	Negative
Black Box Warnings	Fatal and nonfatal pancreatitis have occurred with didanosine alone or in combination with other anti-retroviral agents. Didanosine should be held if pancreatitis is suspected and discontinued if pancreatitis is confirmed. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of antiretroviral nucleoside analogues alone or in combination. Fatal lactic acidosis has been reported in pregnant women who received a combination of didanosine and stavudine. Didanosine and stavudine combination should only be used during pregnancy if the potential benefit clearly outweighs the potential risks.

* For once daily dosing only.

† Twice daily dosing is preferred; however, once daily dosing may be appropriate for patients who require a simplified dosing schedule.

**TABLE II-3
ZALCITABINE (ddC)**

Trade Name	Hivid
Classification	Nucleoside reverse transcriptase inhibitor
Form	0.375-, 0.75-mg tablets
Dosing Recommendations	0.75 mg tid
Food Effect	Absorption is decreased with meal.
Oral Bioavailability	85%
Serum Half-life	1.2 hour
Intracellular Half-life	3 hours
Elimination	Renal excretion 70%
Adverse Events	Peripheral neuropathy Stomatitis Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity.
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Yes (rhesus monkey, 0.30-0.50)
Long-Term Animal Carcinogenicity Studies	Positive (rodent, thymic lymphomas)
Animal Teratogen Studies	Positive (rodent-hydrocephalus at high dose)
Black Box Warnings	Zalcitabine can cause severe peripheral neuropathy; use with caution in patients with pre-existing neuropathy. Zalcitabine may rarely cause pancreatitis, therapy should be held until pancreatitis is excluded. Rare cases of hepatic failure and death have been reported in patients with underlying hepatitis B infection. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of antiretroviral nucleoside analogues alone or in combination.

**TABLE II-4
STAVUDINE (d4T)**

Trade Name	Zerit
Classification	Nucleoside reverse transcriptase inhibitor
Form	15-, 20-, 30-, 40-mg capsules 1 mg/mL for oral solution
Dosing Recommendations	>60 kg: 40 mg bid <60 kg: 30 mg bid
Food Effect	Take without regard to meals.
Oral Bioavailability	86%
Serum Half-life	1.0 hour
Intracellular Half-life	3.5 hours
Elimination	Renal excretion 50%
Adverse Events	Pancreatitis Peripheral neuropathy Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity.
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Yes (rhesus monkey, 0.76)
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative (but sternal bone calcium decreases in rodents)
Black Box Warnings	Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of antiretroviral nucleoside analogues alone or in combination. Stavudine and didanosine combination should only be used during pregnancy if the potential benefit clearly outweighs the potential risks. Fatal lactic acidosis has been reported in pregnant women who received a combination of stavudine and didanosine. Fatal and non-fatal pancreatitis have occurred when stavudine was part of a combination regimen with didanosine with or without hydroxyurea.

**TABLE II-5
LAMIVUDINE (3TC)**

Trade Name	Epivir
Classification	Nucleoside reverse transcriptase inhibitor
Form	100-, 150-mg tablets 5-, 10-mg/mL oral solution
Dosing Recommendation	150 mg bid <50 kg: 2 mg/kg bid or with ZDV as Combivir 1 bid†, or with ZDV and abacavir as Trizivir‡, 1 bid
Food Effect	Take without regard to meals.
Oral Bioavailability	86%
Serum Half-life	3-6 hours
Intracellular Half-life	12 hours
Elimination	Renal excretion unchanged
Adverse Events	(Minimal toxicity) Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity.
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Yes (human, ~1.0)
Long-Term Animal Carcinogenicity Studies	Negative (no tumors, lifetime rodent study)
Animal Teratogen Studies	Negative
Black Box Warnings	Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of antiretroviral nucleoside analogues alone or in combination.

† Each Combivir tablet contains 300 mg ZDV and 150 mg 3TC.

‡ Each Trizivir tablet contains 300 mg ZDV, 150 mg 3TC, and 300 mg abacavir.

**TABLE II-6
ABACAVIR (ABC)**

Trade Name	Ziagen
Classification	Nucleoside reverse transcriptase inhibitor
Form	300-mg tablets 20-mg/mL oral solution
Dosing Recommendations	300 mg bid or with ZDV and 3TC as Trizivir‡, 1 bid
Food Effect	Take without regard to meals. Alcohol increases ABC levels 41%; no effect on alcohol.
Oral Bioavailability	83%
Serum Half-life	1.5 hours
Intracellular Half-life	3.3 hours
Elimination	Metabolized by alcohol dehydrogenase and glucuronyl transferase Renal excretion of metabolites 82%
Adverse Events	Hypersensitivity reaction (can be fatal); fever, rash, nausea, vomiting, malaise or fatigue, and loss of appetite Respiratory symptoms may also be component (sore throat, cough, shortness of breath). Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity with the use of NRTIs.
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Yes (rats)
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Positive [rodent anasarca and skeletal malformations at 1,000 mg/kg (35x human exposure) during organogenesis; not seen in rabbits]
Black Box Warnings	Fatal hypersensitivity reactions reported: <ul style="list-style-type: none"> • Signs or symptoms include: fever, skin rash, fatigue, gastrointestinal symptoms (nausea, vomiting, diarrhea, or abdominal pain), and respiratory symptoms (pharyngitis, dyspnea, or cough). • Abacavir should be discontinued as soon as hypersensitivity reaction is suspected. • Abacavir SHOULD NOT be restarted. If restarted, more severe symptoms will recur within hours and may include life-threatening hypotension and death. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of antiretroviral nucleoside analogues alone or in combination.

‡ Each Trizivir tablet contains 300 mg ZDV, 150 mg 3TC, and 300 mg abacavir.

**TABLE II-7
TENOFIVIR (TDF)**

Trade Name	Viread
Classification	Nucleoside reverse transcriptase inhibitor
Form	300-mg tablets
Dosing Recommendations	300 mg qd Do not use if creatinine clearance <60 mL/min
Food Effect	Increased bioavailability when taken with meal.
Oral Bioavailability	25% in fasting state, 39% with high fat meal
Serum Half-life	17 hours
Intracellular Half-life	10 to 50 hours
Elimination	Primarily renally excreted by glomerular filtration and active tubular secretion
Adverse Event	Asthenia, headache, diarrhea, nausea, vomiting, flatulence Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity with the use of NRTIs.
FDA Pregnancy Category	B
Placental Passage (Newborn:Mother Drug Ratio)	Yes (rat and monkey)
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative (osteomalacia when given to juvenile animals at high doses)
Black Box Warnings	Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs alone or in combination with other antiretrovirals.

**TABLE II-8
NEVIRAPINE (NVP)**

Trade Name	Viramune
Classification	Nucleoside reverse transcriptase inhibitor
Form	200-mg tablets 50 mg/5 mL oral suspension
Dosing Recommendations	200 mg po qd x 14 days, then 200 mg po bid
Food Effect	Take without regard to meals.
Oral Bioavailability	>90%
Serum Half-life	25-30 hours
Elimination	Metabolized by cytochrome P450 (3A inducer); 80% excreted in urine (glucuronidated metabolites, <5% unchanged), 10% in feces
Adverse Events	Rash* Increased transaminase levels Hepatitis
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Yes (human)
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative
Black Box Warnings	Severe, life-threatening hepatotoxicity, including fulminant and cholestatic hepatitis, hepatic necrosis, and hepatic failure. Patients should be advised to seek medical evaluation immediately should signs and symptoms of hepatitis occur. Rare cases of severe, life-threatening, and even fatal skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, and hypersensitivity reactions characterized by rash, constitutional findings, and organ dysfunction have occurred with nevirapine treatment. Patients should be monitored intensively during the first 12 weeks of nevirapine therapy to detect potentially life-threatening hepatotoxicity or skin reactions. A 14-day lead-in period with nevirapine 200 mg daily must be strictly followed. Nevirapine should not be restarted after severe hepatic, skin, or hypersensitivity reactions.

* In clinical trials, the NNRTI was discontinued because of rash in 7% of patients taking nevirapine, 4.3% of patients taking delavirdine, and 1.7% of patients taking efavirenz. Rare cases of Stevens-Johnson syndrome have been reported with the use of all three NNRTIs.

**TABLE II-9
DELAVIDINE (DLV)**

Trade Name	Rescriptor
Classification	Non-nucleoside reverse transcriptase inhibitor
Form	100-mg tablets
Dosing Recommendations	400 mg po tid, or four 100-mg tablets in >3 oz water to produce slurry
Food Effect	Separate dosing with ddi or antacids by 1 hour. Take without regard to meals.
Oral Bioavailability	85%
Serum Half-life	5.8 hours
Elimination	Metabolized by cytochrome P450 (3A inhibitor) 51% excreted in urine (<5% unchanged), 44% in feces
Adverse Events	Rash* Increased transaminase levels Headaches
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Unknown
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Positive (rodent-ventricular septal defect)
Black Box Warnings	None

* In clinical trials, the NNRTI was discontinued because of rash in 7% of patients taking nevirapine, 4.3% of patients taking delavirdine, and 1.7% of patients taking efavirenz. Rare cases of Stevens-Johnson syndrome have been reported with the use of all three NNRTIs.

TABLE II-10
EFAVIRENZ (EFV)

Trade Name	Sustiva
Classification	Non-nucleoside reverse transcriptase inhibitor
Form	50-, 100-, 200-, 600-mg capsules
Dosing Recommendations	600 mg po qhs
Food Effect	Avoid taking after high fat meals, levels increased 50%.
Oral Bioavailability	Data not available
Serum Half-life	40-55 hours
Elimination	Metabolized by cytochrome P450 (3A mixed inducer/inhibitor); 14-34% excreted in urine (glucuronidated metabolites, <1% unchanged), 16-61% in feces.
Adverse Events	Rash* Central nervous systems symptoms† Increase transaminase levels False positive cannabinoid test
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Yes (cynomologus monkey, rat, rabbit) [-1.0]
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Positive (cynomologus monkey-anencephaly, anophthalmia, microphthalmia)
Black Box Warnings	None

* In clinical trials, the NNRTI was discontinued because of rash in 7% of patients taking nevirapine, 4.3% of patients taking delavirdine, and 1.7% of patients taking efavirenz. Rare cases of Stevens-Johnson syndrome have been reported with the use of all three NNRTIs.

† May include dizziness, somnolence, insomnia, abnormal dreams, confusion, abnormal thinking, impaired concentration, amnesia, agitation, depersonalization, hallucinations, and euphoria. The overall frequency of any of these symptoms associated with use of efavirenz was 52% compared with 26% in controls; 2.6% of those on efavirenz discontinued the drug because of these symptoms; symptoms usually subside spontaneously over 2-4 weeks.

**TABLE II-11
INDINAVIR (IDV)**

Trade Name	Crixivan
Classification	Protease inhibitor
Form	200-, 333-, 400-mg caps
Dosing Recommendations	800 mg q8h Separate dosing with ddl by 1 hour
Food Effect	Levels decrease 77% Take 1 hour before or 2 hours after meals; may take with skim milk or low fat meal.
Oral Bioavailability	65%
Serum Half-life	1.5–2 hours
Route of Metabolism	P450 cytochrome 3A4 inhibitor (less than ritonavir)
Storage	Room temperature
Adverse Events	Nephrolithiasis GI intolerance, nausea Lab: Increased indirect bilirubinemia (inconsequential) Misc: Headache, asthenia, blurred vision, dizziness, rash, metallic taste, thrombocytopenia Hyperglycemia† Fat redistribution and lipid abnormalities‡ Possible increased bleeding episodes in patients with hemophilia
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Yes (rats, rabbits) [substantial in rats, low in rabbits]
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative (but extra ribs in rodents)
Black Box Warnings	None

† Cases of worsening glycemic control in patients with pre-existing diabetes, and cases of new-onset diabetes including diabetic ketoacidosis have been reported with the use of all protease inhibitors.

‡ Discontinuation of PIs may be required to reverse fat redistribution. Patients with hypertriglyceridemia or hypercholesterolemia should be evaluated for risks for cardiovascular events and pancreatitis.

TABLE II-12 RITONAVIR (RTV)	
Trade Name	Norvir
Classification	Protease inhibitor
Form	100-mg caps 600 mg/7.5 mL po solution
Dosing Recommendations	600 mg q12h* Separate dosing with ddI by 2 hours
Food Effect	Levels increase 15% Take with food if possible, this may improve tolerability.
Oral Bioavailability	(not determined)
Serum Half-life	3–5 hours
Route of Metabolism	P450 cytochrome 3A4 > 2D6 Potent 3A4 inhibitor
Storage	Refrigerate capsules. Oral solution should NOT be refrigerated.
Adverse Events	GI intolerance, nausea, vomiting, diarrhea Paresthesias – circumoral and extremities Hepatitis Pancreatitis Asthenia Taste perversion Lab: Triglycerides increase >200%, transaminase elevation, elevated CPK and uric acid Hyperglycemia† Fat redistribution and lipid abnormalities‡ Possible increased bleeding episodes in patients with hemophilia
FDA Pregnancy Category	B
Placental Passage (Newborn:Mother Drug Ratio)	Yes (rats) [mid-term fetus, 1.15; late-term fetus, 0.15-0.64]
Long-Term Animal Carcinogenicity Studies	Positive (rodent, liver adenomas and carcinomas in male mice)
Animal Teratogen Studies	Negative (but cryptorchidism in rodents)
Black Box Warnings	Co-administration of ritonavir with certain medications may result in potentially serious and/or life-threatening adverse events due to effects of ritonavir on hepatic metabolism of certain drugs.

* Dose escalation for ritonavir: Day 1-2: 300 mg bid; day 3-5: 400 mg bid; day 6-13: 500 mg bid; day 14: 600 mg bid. Combination treatment regimen with saquinavir (400 mg po bid) plus ritonavir (400 mg po bid).

† See footnote on page II-12.

‡ See footnote on page II-12.

TABLE II-13
NELFINAVIR (NFV)

Trade Name	Viracept
Classification	Protease inhibitor
Form	250-mg tablets 50 mg/g oral powder
Dosing Recommendations	750 mg tid or 1,250 bid
Food Effect	Levels increase 2-3 fold Take with meal or snack.
Oral Bioavailability	20-80%
Serum Half-life	3.5–5 hours
Route of Metabolism	P450 cytochrome 3A4 inhibitor (less than ritonavir)
Storage	Room temperature
Adverse Events	Diarrhea Hyperglycemia† Fat redistribution and lipid abnormalities‡ Possible increased bleeding episodes in patients with hemophilia
FDA Pregnancy Category	B
Placental Passage (Newborn:Mother Drug Ratio)	Unknown
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative
Black Box Warnings	None

† Cases of worsening glycemic control in patients with pre-existing diabetes, and cases of new-onset diabetes including diabetic ketoacidosis have been reported with the use of all protease inhibitors.

‡ Discontinuation of PIs may be required to reverse fat redistribution. Patients with hypertriglyceridemia or hypercholesterolemia should be evaluated for risks for cardiovascular events and pancreatitis.

TABLE II-14
LOPINAVIR/RITONAVIR (LPV/RTV)

Trade Name	Kaletra
Classification	Protease inhibitor
Form	133.3 mg lopinavir + 33.3 mg ritonavir capsules 80 mg lopinavir + 20 mg ritonavir per mL oral solution
Dosing Recommendations	400 mg lopinavir + 100 mg ritonavir bid
Food Effect	Moderate fat meal increases AUC of capsules and solution by 48% and 80%, respectively. Take with food.
Oral Bioavailability	Not determined in humans
Serum Half-life	5-6 hours
Route of Metabolism	P450 cytochrome 3A4 inhibitor
Storage	Refrigerated capsules stable until date on label. If stored at room temperature, stable for 2 months.
Adverse Events	GI intolerance, nausea, vomiting, diarrhea Asthenia Elevated transaminase enzymes Hyperglycemia† Fat redistribution and lipid abnormalities‡ Possible increased bleeding episodes in patients with hemophilia Oral solution contains 42% alcohol
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Unknown
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative (but delayed skeletal ossification and increase in skeletal variations in rats at maternally toxic doses)
Black Box Warnings	None

† Cases of worsening glycemic control in patients with pre-existing diabetes, and cases of new-onset diabetes including diabetic ketoacidosis have been reported with the use of all protease inhibitors.

‡ Discontinuation of PIs may be required to reverse fat redistribution. Patients with hypertriglyceridemia or hypercholesterolemia should be evaluated for risks for cardiovascular events and pancreatitis.

TABLE II-15
SAQUINA VIR (SQV) – INVIRASE

Trade Name	Invirase
Classification	Protease inhibitor
Form	200-mg caps
Dosing Recommendations	400 mg bid with ritonavir; Invirase not recommended otherwise
Food Effect	Take within 2 hours after a full meal.
Oral Bioavailability	Hard gel capsule: 4% erratic
Serum Half-life	1-2 hours
Route of Metabolism	P450 cytochrome 3A4 inhibitor (less than ritonavir)
Storage	Room temperature
Adverse Events	GI intolerance, nausea, and diarrhea Headache Elevated transaminase enzymes Hyperglycemia† Fat redistribution and lipid abnormalities‡ Possible increased bleeding episodes in patients with hemophilia
FDA Pregnancy Category	B
Placental Passage (Newborn:Mother Drug Ratio)	Minimal (rats, rabbits)
Black Box Warnings	None

† Cases of worsening glycemic control in patients with pre-existing diabetes, and cases of new-onset diabetes including diabetic ketoacidosis have been reported with the use of all protease inhibitors.

‡ Discontinuation of PIs may be required to reverse fat redistribution. Patients with hypertriglyceridemia or hypercholesterolemia should be evaluated for risks for cardiovascular events and pancreatitis.

TABLE II-16
SAQUINA VIR (SQV) – FORTOVASE

Trade Name	Fortovase
Classification	Protease inhibitor
Form	200-mg caps
Dosing Recommendations	1200 mg tid
Food Effect	Take with meals or up to 2 hours after meals.
Oral Bioavailability	Soft-gel capsule (not determined)
Serum Half-life	1-2 hours
Route of Metabolism	P450 cytochrome 3A4 inhibitor (less than ritonavir)
Storage	Refrigerate or store at room temperature (up to 3 months).
Adverse Events	GI intolerance, nausea, diarrhea, abdominal pain, and dyspepsia Headache Elevated transaminase enzymes Hyperglycemia† Fat redistribution and lipid abnormalities‡ Possible increased bleeding episodes in patients with hemophilia
FDA Pregnancy Category	B
Placental Passage (Newborn:Mother Drug Ratio)	Minimal (rats, rabbits)
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative
Black Box Warnings	None

† Cases of worsening glycemic control in patients with pre-existing diabetes, and cases of new-onset diabetes including diabetic ketoacidosis have been reported with the use of all protease inhibitors.

‡ Discontinuation of PIs may be required to reverse fat redistribution. Patients with hypertriglyceridemia or hypercholesterolemia should be evaluated for risks for cardiovascular events and pancreatitis.

TABLE II-17
AMPRENAVIR (APV)

Trade Name	Agenerase
Classification	Protease inhibitor
Form	50-, 150-mg capsules 15 mg/mL oral solution (tabs and solution NOT interchangeable on mg per mg basis)
Dosing Recommendations	1200 mg bid
Food Effect	High fat meal decreases AUC 21%; can be taken with or without food, but high fat meal should be avoided.
Oral Bioavailability	Not determined in humans
Serum Half-life	7.1-10.6 hours
Route of Metabolism	P450 cytochrome 3A4 inhibitor (less than ritonavir; similar to indinavir, nelfinavir)
Storage	Room temperature
Adverse Events	GI intolerance, nausea, vomiting, diarrhea Rash Oral paresthesias Lab: Increase in liver function tests Hyperglycemia† Fat redistribution and lipid abnormalities‡ Possible increased bleeding episodes in patients with hemophilia
FDA Pregnancy Category	C
Placental Passage (Newborn:Mother Drug Ratio)	Unknown
Long-Term Animal Carcinogenicity Studies	Not completed
Animal Teratogen Studies	Negative (but deficient ossification and thymic elongation in rats and rabbits)
Black Box Warnings	Because of the potential risk of toxicity from large amounts of the excipient propylene glycol in Agenerase Oral Solution, it is contraindicated in the following patient populations: <ul style="list-style-type: none"> • children age <4 years • pregnant women • patients with renal or hepatic failure • patients treated with disulfiram or metronidazole Oral solution should be used only when Agenerase capsules or other protease inhibitors cannot be used.

† See footnote on page II-12.

‡ See footnote on page II-12.

FDA PREGNANCY CATEGORIES

- A** Adequate and well-controlled studies of pregnant women fail to demonstrate a risk to the fetus during the first trimester of pregnancy (and there is no evidence of risk during later trimesters).
- B** Animal reproduction studies fail to demonstrate a risk to the fetus and adequate and well-controlled studies of pregnant women have not been conducted.
- C** Safety in human pregnancy has not been determined, animal studies are either positive for fetal risk or have not been conducted, and the drug should not be used unless the potential benefit outweighs the potential risk to the fetus.
- D** Positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experiences, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks.
- X** Studies in animals or reports of adverse reactions have indicated that the risk associated with the use of the drug for pregnant women clearly outweighs any possible benefit.

APPENDIX IX
RECOMMENDATIONS FOR THE USE OF
ANTIRETROVIRAL THERAPY DURING PREGNANCY TO
REDUCE RISK OF MOTHER-TO-CHILD HIV TRANSMISSION*

	Antiretroviral Naïve Women	Women Receiving HAART
Viral load <1,000 copies/mL	Recommend 3-part zidovudine regimen. Offer HAART without recommendation.	Continue HAART unless contraindicated. Include zidovudine if possible. Find alternatives to efavirenz, hydroxyurea, combination didanosine/stavudine.
Viral load >1,000 copies/mL	Recommend HAART that includes the 3-part zidovudine regimen.	Assess adherence. Perform resistance testing to help determine optimal regimen. Recommend new HAART. Find alternatives to efavirenz, hydroxyurea, combination didanosine/stavudine.

* Recommendations for antiretroviral therapy for maternal indications can be found in Chapter 1: *Antiretroviral Therapy for Adults*. Women presenting during the first trimester may choose to continue or start antiretroviral therapy at presentation, or may delay or discontinue it until after the first trimester.

APPENDIX X
DOSING GUIDELINES FOR THE USE OF ZIDOVUDINE
ALONE OR AS PART OF HAART TO REDUCE RISK OF
MOTHER-TO-CHILD HIV TRANSMISSION

Timing	Dosing
Prenatal	Zidovudine 200 mg PO tid or Zidovudine 300 mg PO bid
Intrapartum	<p>Intravenous zidovudine 2 mg/kg loading dose over 1/2 to 1 hour, followed by a continuous infusion of zidovudine 1 mg/kg/hour IV until the cord is clamped.</p> <p>For women undergoing elective cesarean section, intravenous zidovudine should be started at least 3 hours prior to surgery.</p> <p>If delivery is anticipated within 1/2 hour of arrival, a bolus of intravenous zidovudine may be given.</p> <p>Intravenous zidovudine may be mixed in normal saline, D5 normal saline, lactated ringers, or D5 lactated ringers to a maximal concentration of 4 mg/mL.</p>
Newborn	<p>Zidovudine 2 mg/kg PO q6h for 6 weeks.</p> <p>For infants receiving zidovudine with lamivudine, dosage of zidovudine 4 mg/kg q 12 h for 7 days has been used successfully.</p> <p>For infants unable to tolerate PO, intravenous zidovudine 1.5 mg/kg can be given over 1/2 hour q6h.</p> <p>For premature infants <37 weeks' gestation, zidovudine dosage should be reduced to 1.5 mg/kg PO q12h for the first 2 weeks of life.</p>

APPENDIX XI
RECOMMENDATIONS FOR PROPHYLAXIS TO REDUCE
MOTHER-TO-CHILD TRANSMISSION WHEN MOTHER HAS
NOT RECEIVED PRENATAL ANTIRETROVIRAL THERAPY*

	Prenatal	Intrapartum	Newborn
Option 1	No Antiretroviral	ZDV 2 mg/kg IV loading dose over 1/2 to 1 hour followed by continuous infusion of 1 mg/kg IV per hour until the cord is clamped.	ZDV syrup, 2 mg/kg PO every 6 hours for 6 weeks. Initiate as soon as possible after birth.
Option 2	No Antiretroviral	Nevirapine 200 mg PO at start of labor.	Nevirapine 2 mg/kg PO once at 48 hours.
Option 3	No Antiretroviral	ZDV 600 mg PO at start of labor followed by 300 mg PO every 3 hours and lamivudine 150 mg PO at start of labor and 150 mg PO every 12 hours until delivery.	ZDV 4 mg/kg PO every 12 hours and lamivudine 2 mg/kg every 12 hours for 7 days. Initiate as soon as possible after birth.
Option 4†	No Antiretroviral	Add to option 1: nevirapine 200 mg PO at start of labor (1 dose only).	Add to option 1: nevirapine 2 mg/kg PO once at age 48 hours.

* There are no clinical trials describing efficacy of newborn only ARV therapy. When the mother has not received prenatal or intrapartum ARV therapy, consider any of the four options above for newborn therapy. If nevirapine is given to the newborn when the mother has not received it, nevirapine should be initiated as soon as possible after birth. ARV prophylaxis is unlikely to be efficacious beyond 48 hours after birth.

† There are no clinical trial data to support option 4.

APPENDIX XII

PROTOCOL FOR EXPEDITED HIV TESTING FOR USE BY LABOR, DELIVERY, AND NURSERY UNITS

PRENATAL RECORD REVIEW

- Expedited HIV testing is not required:
 - If there is documentation of a negative HIV test conducted during the current pregnancy;
 - If the pregnant woman is known to be HIV-infected.
- Review the prenatal record as soon as it is received by the labor and delivery unit.
- Before admission: Determine the need for expedited HIV testing:
 - If no documentation of HIV testing during the current pregnancy exists, request that the prenatal provider counsel the woman and recommend HIV testing as soon as possible.
- Review the medical record at the time that the woman is admitted to the labor unit
 - If there is no documentation of an HIV test result obtained during her current pregnancy (and she is not known to be HIV positive), telephone the prenatal care provider immediately for HIV test history.
- Using the instructions provided, complete the form, "Test History and Assessment" (DOH 4068).

PRE-TEST COUNSELING FOR EXPEDITED HIV TESTING

Women who are candidates for expedited testing should receive pre-test counseling, which includes:

- A brief explanation of the nature of AIDS and HIV-related illness.
- A discussion of perinatal HIV transmission.
- A discussion of the effectiveness of antiretroviral therapy in reducing HIV transmission, including the likely effectiveness of abbreviated antiretroviral regimens.
- A discussion of newborn HIV testing, including:
 - All newborns born in New York State are tested for HIV, and the results are reported to their mothers.

- Mothers not HIV-tested during the current pregnancy must be offered the opportunity to consent to expedited HIV testing in the labor and delivery setting.
- If the mother does not consent to expedited testing in labor, her newborn will be tested for HIV immediately after birth without consent.
- An explanation of the meaning of a positive maternal or newborn test result.
- An explanation of the meaning of the expedited test result, the chance of a false-positive result (based on the specific test algorithm used by the facility), and the necessity and importance of confirmatory testing.

EXPEDITED HIV TESTING OF MOTHERS AND/OR NEWBORNS

- If the mother agrees to be tested, obtain written informed consent using the DOH consent form, “Informed Consent to Perform an Expedited Test in the Delivery Setting” (DOH 4158).
- If the mother does not agree to be tested or if there is no time for testing before delivery, inform the mother that her newborn will be tested immediately after birth.
- Draw a sufficient sample of blood to complete screening and to allow confirmatory testing if the screen is positive.
- Transmit the sample to the laboratory with a signed request to ask that the laboratory report a preliminary result.
- Complete the Expedited Testing Status portion of the “Test History and Assessment” form (DOH 4068), and transfer the information to the HIV boxes on the “Newborn Screening Blood Collection” form (DOH 1514).

BREASTFEEDING

- If the HIV preliminary test result is not returned by the time the mother would initiate breastfeeding, counsel her about the risk of HIV transmission through breastfeeding if she is HIV-infected.

NEGATIVE MATERNAL OR NEWBORN HIV SCREENING TEST

RESULTS

- Report the negative test result to the mother as soon as it is available.

- Inform the mother that the test result means that she is not infected and that her newborn has not been exposed to HIV.
- Explain that further (confirmatory) testing is not necessary for negative screening results.

PRELIMINARY POSITIVE MATERNAL OR NEWBORN HIV TEST

RESULTS

- Inform the mother in person that the preliminary HIV test result is positive and that there exists the possibility that she is HIV-infected and that her newborn has been exposed to HIV.
- Inform the mother that a confirmatory test has been ordered. Give her an approximate time (days/hours) for when the confirmatory test result will be available.
- Advise the mother not to begin or continue breastfeeding her newborn until the confirmatory test is performed. (Mother can pump her breast and discard the milk until the confirmatory test returns.)
- Discuss with the mother the likelihood that the test result is a true positive (based on the prevalence of HIV infection in the community and among women who deliver at the facility and on an assessment of the mother's personal risk).
- Discuss with the mother the risks and benefits of antiretroviral prophylaxis administered during labor or to the newborn, as applicable.
- Initiate intrapartum or newborn antiretroviral prophylaxis as soon as possible. Treatment with antiretroviral medication follows the same general consent procedures as any medical treatment.

DISCHARGE

- Consider delaying discharge when:
 - The mother's or newborn's expedited HIV test result is not available.
 - The preliminary test result is positive but the confirmatory test results are not yet available.
- Develop a follow-up plan for those who are discharged that includes referrals for medical and support services.
- Document the discharge plan in the medical record.

NEGATIVE MATERNAL OR NEWBORN CONFIRMATORY HIV TEST

RESULTS

- Report the result in person to the mother or the person authorized to consent to health care for the newborn.
- Advise the mother that the preliminary test result was a false-positive result and that she is not infected with HIV.
- Reassure her that false-positive results can occur with expedited tests for HIV.
- Discontinue ZDV prophylaxis.
- Ensure that the child's pediatrician is aware that a short course of ZDV was given due to a false-positive HIV test result.
- If mother wants to breastfeed, refer her to a lactation consultant for assistance.

POSITIVE MATERNAL OR NEWBORN CONFIRMATORY HIV TEST

RESULTS

- Provide the test result in person to the mother or person authorized to consent to health care for the newborn.
- Inform the mother that the confirmatory HIV test is positive, which means that she is infected with HIV and that her newborn has been exposed to HIV and may or may not be infected.
- If ZDV has been administered during labor and delivery or to the newborn, remind the mother that the chances that the newborn is HIV-infected are approximately one in ten.
- Provide the mother with post-test counseling, including:
 - Support for coping with the emotional impact of receiving the positive test result.
 - Referrals to mental health services if indicated (if the mother is an adolescent, consider referral to an agency that provides specialized mental health services for adolescents).
 - Counseling against breastfeeding.
 - Information regarding available medical treatment for both the mother and child.
 - A discussion of potential discrimination problems and protections.
 - Screening for domestic violence potential.

- An offer of assistance in notifying the mother's spouse/partner and determining the HIV status of other children.
 - Information on behavior change to prevent HIV transmission.
- Arrange for follow-up care for both the mother and the infant prior to discharge.
 - The newborn should be referred to a pediatric HIV Specialist for further testing and treatment.
 - The mother should be referred to an adult HIV Specialist.
- Arrange for an immediate DNA polymerase chain reaction (PCR) test for the infant. PCR testing is available free of charge from the New York State Department of Health's Wadsworth Center (phone no, 518-474-7068) for all HIV-exposed infants born in New York State.
- Provide a prescription for or supply of ZDV for the newborn. Instruct the mother or infant's caregiver on administration, side effects, and duration of therapy (until age 6 weeks) as well as whom to contact if she encounters difficulty in administering the ZDV to her infant. Monitor the child for weight gain and adjust ZDV dose accordingly.

**DEPARTMENT OF HEALTH REPORTING REQUIREMENTS FOR
PRELIMINARY POSITIVE RESULTS**

- Complete DOH form, "Maternal-Pediatric HIV Prevention and Care Program, Report on Preliminary Positive HIV Results" (DOH 4159) and fax to the Department of Health as per instructions on the form. This report must be submitted for each case of a preliminary positive HIV test result whether or not the confirmatory test is positive.