

GUIDELINES FOR THE INTRAPARTUM AND POSTNATAL MANAGEMENT OF WOMEN WITH KNOWN OR SUSPECTED HIV INFECTION AND THEIR NEWBORNS (Code 45 Protocol)

If you have any questions about this protocol, please call the Maternal Child and Adolescent HIV Management and Research Program or any of the following providers:

MCA Program

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Code 45 Guidelines: Overview and Treatment Recommendations

This protocol is for known HIV infected pregnant women (referred to as Code 45) and their newborns admitted to Women's and Children's Hospital (WCH), LAC+USC Medical Center. It is also for pregnant women (and their newborns) who are admitted to WCH and test HIV-positive with a rapid HIV test at labor and delivery.

Purpose

The Maternal Child and Adolescent (MCA) HIV Management and Research Center provides comprehensive multidisciplinary care for HIV-infected women, children and adolescents and their families. This protocol is a collaboration of the Departments of Obstetrics and Gynecology, Internal Medicine, and Pediatrics. The goal is to prevent perinatal transmission of HIV infection from HIV-infected pregnant women to their infants.

Goal

1. To prevent perinatal transmission of HIV infection and ensure early diagnosis of the infant by:
 - Providing state-of-the-art maternal and infant anti-retroviral therapies.
 - Achieving a high circulating level of appropriate antiretroviral therapy throughout labor and delivery.
 - Providing appropriate antiretroviral prophylaxis to the newborn.
 - Initiating laboratory tests and procedures for early diagnosis of HIV infection in the newborn.
 - Identifying women in labor with undiagnosed HIV infection through the use of rapid HIV testing.
2. To provide antiretroviral therapy appropriate for maternal and fetal health.
3. To monitor and identify treatment-related toxicities.
4. To monitor and evaluate the effect of clinical, virologic, and immunologic factors on the transmission and pathogenesis of HIV and concomitant infections among HIV-infected women and their infants.

Protocol Summary

The treatments and procedures described in this protocol are based primarily on the findings of a study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) and are now updated on a regular basis. This study, the AIDS Clinical Trials Group (ACTG) Protocol 076, demonstrated a decrease in the HIV transmission rate among a selected group of HIV-

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infected pregnant women from 25% in the placebo group to 8% in the group receiving antepartum, intrapartum, and neonatal ZDV. The US Public Health Service's (PHS's) review of the available data and guidelines regarding the use of antiretrovirals to reduce perinatal transmission were published in the MMWR in August 1994, and are updated on an ongoing basis, most recently in February 2005. The following website contains the most recent treatment guidelines: (<http://www.aidsinfo.nih.gov/guidelines/>).

A COPY OF THE MOST RECENT GUIDELINES IS AVAILABLE IN A BINDER IN THE RESIDENTS' LOUNGE ON 5L, LABOR AND DELIVERY.

Following the availability of other antiretroviral agents, specialized centers such as ours have achieved 0-2% transmission rates when multiple agents are used. In our experience and the experience of others, mothers who receive highly active anti-retroviral therapy (HAART) with adequate suppression of viral replication have a very low risk of vertical transmission. Elective C-section is recommended in some cases to reduce this risk.

Code 45 pregnant women in labor admitted to Women's and Children's Hospital fall into the following four categories: Women with: 1) HIV-1 RNA (viral load <50 copies/mL if using an ultra-sensitive test or <400 copies/mL if using a standard test; 2) HIV-1 RNA >50 copies/mL if using an ultra-sensitive test or >400 copies/mL if using a standard test; 3) unknown HIV-1 RNA but known HIV status; and, 4) unknown HIV status.

As per the **Public Health Service Recommendations**: "The three-part ZDV chemoprophylaxis regimen, initiated after the first trimester, should be recommended for all pregnant women with HIV infection regardless of antenatal HIV RNA copy number to reduce the risk for perinatal transmission. The combination of ZDV chemoprophylaxis with additional antiretroviral drugs for treatment of HIV infection is recommended for infected women whose clinical, immunologic or virologic status requires treatment or who have HIV RNA over 1,000 copies/mL regardless of clinical or immunologic status. Women who are in the first trimester of pregnancy may consider delaying initiation of therapy until after 10-12 weeks' gestation."

Most HIV-infected pregnant women who receive their prenatal care at the MCA Center are receiving HAART as this has not been found to affect pregnancy outcome adversely, maintains maternal health, and reduces the risk of vertical transmission of HIV. In general, these patients have a known viral load and CD4 count, and based on these, a plan has already been made for the management of their labor and delivery, and the subsequent treatment of the neonate. In almost all cases, intravenous ZDV is given to the mother during labor and delivery. The exceptions are a known adverse reaction to ZDV or maternal refusal to take ZDV; in these cases, oral or IV ZDV is given to the neonate starting as soon as possible after delivery. Mothers will generally receive their other antiretrovirals during labor, so as to maintain adequate blood levels during the period around delivery and adequate blood levels when possible in the baby.

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Possible Adverse Effects of Antiretroviral Therapy

Recently there has been increasing concern over the potential toxicity of antiretroviral therapy to the (pregnant) woman, fetus, and baby. Some authorities, notably in Europe, are concerned that HAART (Highly Active Antiretroviral Therapy) during pregnancy increases the risk of adverse pregnancy outcomes such as premature delivery, intrauterine growth retardation, and fetal demise, and recommend alternative forms of treatment/prophylaxis for certain low-risk situations. We have not experienced an increased level of adverse pregnancy outcomes in our patient population exposed to HAART. Therefore, in our opinion the potential benefits of HAART during pregnancy, that is, control of maternal HIV disease, and prevention of vertical transmission, outweigh the potential risks, and so HAART in pregnancy remains our standard of care, and is also the standard of care in most other centers providing prenatal care for HIV-infected women in the United States. However, those who provide care for these patients must be aware of the possible adverse effects and toxicity of antiretroviral therapy in the pregnant woman, fetus, and neonate. Patients must be counseled as to the benefits and potential risks of such therapy as well.

Nucleoside analogue reverse transcriptase inhibitors (NRTIs): Zidovudine (ZDV) has many potential adverse effects including malaise, nausea, fatigue, headache, and toxicities such as bone marrow suppression, myopathy, cardiomyopathy, and lactic acidosis. NRTI drugs such as ZDV are incorporated into host DNA, both cellular and mitochondrial, and may interfere with cellular processes related to DNA. This property may be the cause of much of the toxicity related to these drugs. Lactic acidosis in particular may be caused by mitochondrial toxicity of NRTIs. In addition, their integration into human DNA raises the concern of teratogenicity, mutagenicity, and carcinogenicity. Thankfully, serious toxicity related to NRTI drugs either in adults, children, or fetuses is rare, and syndromes of fetal teratogenicity or carcinogenicity in humans have not been observed.

Non-nucleoside analogue reverse transcriptase inhibitor antiretroviral drugs (NNRTIs): NNRTIs have many adverse effects and toxicities as well, the most common being rash (for nevirapine) and the most serious being hepatotoxicity, which can rarely be fatal. One NNRTI, efavirenz, was associated with anencephaly and severe craniofacial abnormalities in cynomolgus monkey fetuses exposed to it, several cases of neural tube defects have been described in human fetuses with 1st trimester efavirenz exposure. Prospectively collected data from the Antiretroviral Pregnancy Register have not yet demonstrated an increased risk of congenital anomalies; this study is ongoing. Efavirenz has recently been assigned FDA pregnancy category D designation. There is currently no evidence of adverse fetal effects with use of efavirenz after the first trimester. To date, there is no evidence of teratogenicity associated with nevirapine.

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Protease inhibitors (PIs): PI antiretroviral drugs have frequent adverse effects, the most common being nausea, vomiting, abdominal pain, diarrhea, and malaise. As a group they have been recently shown to be associated with abnormalities of glucose and lipid metabolism, causing a variety of syndromes including hyperglycemia, hyperlipidemia, hypercholesterolemia, and abnormal body fat distribution in various combinations. PIs as a group have so far not been found to cause fetal toxicity or teratogenicity.

HAART in pregnancy: With the exception of efavirenz, which is pregnancy category D and should be avoided, all FDA approved antiretroviral drugs, including ZDV, are currently pregnancy category class B or C. There are, however, concerns about the use of some of these drugs in pregnancy. As mentioned earlier, the current standard of care at our center, and at most North American centers with regard to antiretroviral therapy in pregnancy is to continue HAART with the exception of efavirenz, for women already on it (but adding or substituting ZDV if the patient is not receiving it, if possible), and to offer HAART to women not yet on it, at least after the first trimester. Appropriate counseling as to the potential risks for pregnancy and the fetus should be provided to the pregnant woman, so that she may make an informed decision. The indications for and potential risks of the antiretroviral therapy to be provided to the neonate should be discussed with the pregnant woman prior to delivery and again after delivery, before discharge from the hospital.

Monitoring for adverse effects of therapy: The pregnant women, fetus, neonate, and infant should be monitored carefully for signs of adverse effects, toxicity, and teratogenicity related to the antiretroviral therapy given. Maternal monitoring should include evaluation for hepatotoxicity, anemia and lactic acidosis. In particular the neonate should be monitored for evidence of mitochondrial toxicity related to ZDV, and hepatotoxicity related to any antiretroviral drug. Persistent metabolic acidosis in the neonate should raise the concern of mitochondrial toxicity and resultant lactic acidosis. Any possible toxicity or teratogenicity due to antiretroviral therapy should be reported immediately to the appropriate MCA staff.

Treatment Recommendations

Consultation with both the obstetrical and pediatric MCA staff is required for all HIV-infected pregnant women admitted to the hospital in labor. In general, the following are the recommended guidelines for all HIV-infected women in labor based on **maternal HIV-1 RNA level at or near delivery**:

- 1) **HIV-1 RNA (VIRAL LOAD) <50 copies/mL if using an ultra-sensitive test or <400 copies/mL if using a standard test and with prenatal care and anti-retroviral therapy (ART).**
 - a) ***Continue current ART regimen during labor and delivery. If patient's current regimen contains d4T (stavudine, Zerit), it must be discontinued at the time of admission.***

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- b) **Intravenous (IV) ZDV** (AZT, Retrovir) should be initiated and continued throughout labor and delivery. (Loading dose: 2mg/kg to infuse over one hour, then maintenance dose: 1 mg/kg/hr). If unable to administer IV ZDV: use oral ZDV 600 mg loading, then 300 mg q 3 hours.
- c) **Neonatal ZDV therapy** (2 mg/kg every 6 hours) should be initiated as soon as possible after delivery. For babies unable to tolerate oral ZDV, IV ZDV can be given at dose 1.5 mg/kg q 6 hrs. Premature infants (estimated gestational age < 34 weeks) require lower dosing at 1.5 mg/kg every 12 hours from birth to two weeks of age; after 14 days of age the dose can be increased to 2 mg/kg every 8 hours.
- 2) **HIV-1 RNA >50 copies/mL if using an ultra-sensitive test or >400 copies/mL if using a standard test and with prenatal care and anti-retroviral therapy :**
- a) **Continue current ART regimen during labor and delivery. If patient's current regimen contains d4T (stavudine, Zerit), it must be discontinued at the time of admission.** If patient is not on ART, start IV ZDV (AZT, Retrovir) and additional anti-retrovirals as under (2d) below.
- b) **Intravenous ZDV** (AZT, Retrovir) should be initiated and continued throughout labor and delivery (Loading dose: 2mg/kg to infuse over one hour, then maintenance dose: 1 mg/kg/hr). If unable to administer IV ZDV: use oral ZDV 600 mg loading, then 300 mg q 3 hours.
- c) **Neonatal ZDV therapy** (2 mg/kg every 6 hours) should be initiated as soon as possible after delivery. Additional guidelines on neonatal ZDV dosing are outlined in section 1c.
- d) **Consider additional antiretrovirals** after consultation with an MCA physician:
- i) **A single oral dose of nevirapine** (a non-nucleoside reverse transcriptase inhibitor) **to both mother (200 mg) and infant (2 mg/kg at 48-72 hrs.)** may be added because of high potency, ease of administration, and advantageous pharmacokinetics.
- ii) **Additional antiretroviral agents** to the mother and/or infant may be added as indicated and after consultation with the on-call MCA staff member.
- e) **Elective cesarean section**, may reduce vertical transmission and may be offered after consultation with MCA staff. **ELECTIVE CESAREAN DELIVERY SHOULD BE ENCOURAGED FOR VIRAL LOADS >1000 copies/mL.** However, elective cesarean section does not obviate the need for antiretroviral therapy to the mother during the period around delivery and to the baby during the postnatal period.
- 3) **HIV-infected woman with unknown RNA (VIRAL LOAD) status:**
If the woman **received prenatal antiretroviral therapy (ART)**, follow procedures described in (2a-e) above.

Code 45 Guidelines: Overview and Treatment Recommendations (cont)

If woman **did not receive prenatal ART and arrives in labor:**

- a) Start intravenous ZDV (AZT, Retrovir) and additional anti-retrovirals as under (3d) below.
- b) **Intravenous ZDV** (AZT, Retrovir) should be initiated and continued throughout labor and delivery (Loading dose: 2mg/kg to infuse over one hour, then maintenance dose: 1 mg/kg/hr). If unable to administer IV ZDV: use oral ZDV 600 mg loading, then 300 mg q 3 hours.
- c) **Neonatal ZDV therapy** (2 mg/kg every 6 hours) should be initiated as soon as possible after delivery. Additional guidelines on neonatal ZDV dosing are outlined in section 1c.
- d) **Consider additional antiretrovirals** after consultation with an MCA physician:
 - i) **A single oral dose of nevirapine** (a non-nucleoside reverse transcriptase inhibitor) **to both mother (200 mg) and infant (2/mg/kg at 48-72 hrs.)** may be added because of high potency, ease of administration, and advantageous pharmacokinetics.
 - ii) **Additional antiretroviral agents** to the mother and/or infant may be added as indicated and after consultation with the on-call MCA staff member.
- e) **Elective cesarean section** may reduce vertical transmission and may be offered after consultation with MCA staff. However, elective cesarean section does not obviate the need for antiretroviral therapy to the mother during the period up to and including labor and delivery and to the baby during the postnatal period.

If the woman **did not receive ART during labor and delivery:**

- a) **Neonatal ZDV (AZT, Retrovir) therapy** should be initiated immediately as outlined in section 1c.
- b) **A single dose of nevirapine of 2 mg/kg to the infant** should be initiated as soon as possible after the baby is able to receive oral medications. Additional doses of nevirapine may be given upon consultation with an MCA physician.
- c) **Other anti-retrovirals for the infant** may also be considered in this situation, in particular, lamivudine (3TC) after consultation with an MCA physician.
- d) The mother should be referred to the MCA Clinic to evaluate starting anti-retroviral therapy post-partum.

4) **HIV status unknown**

- a) All women in labor should be asked about their HIV status when their history is taken, if it is not already known.
- b) **All pregnant women presenting to the hospital who have no HIV test result documented in the chart or in the Laboratory Computer, and in whom delivery is anticipated within several days should be encouraged to have a rapid HIV test. California state law requires the obstetrical care provider to do an HIV test with the woman's consent. She has the right to refuse the test. The provider must document in the chart whether the HIV test was done and the result, both**

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- during prenatal care and on admission for delivery if no result is available from prenatal care.**
- c) Women with a negative HIV result in their chart or in the Laboratory Computer, but who are at exceptionally high risk for HIV and the negative HIV result is more than two months old, should also be encouraged to be retested with the rapid test at admission to Labor and Delivery.
 - d) If the rapid test is positive, follow the guidelines in #3 above (HIV- infected women with unknown RNA status). Treatment should be given to prevent transmission even though a confirmatory HIV test result may not yet be available.
 - e) If a women in labor is of unknown HIV status and she has strong risk factors (no prenatal care, IDU, HIV-infected partner, drug use, commercial sex worker) and/or has examination or laboratory abnormalities suggestive of HIV infection (oral thrush, generalized adenopathy, wasting, severe anemia, thrombocytopenia, elevated globulin fraction), then a rapid HIV test, HIV RNA PCR, and T cell subsets should be done.
 - f) If the mother whose HIV status is unknown refuses rapid HIV testing, this testing should be offered for her newborn.
 - g) If it is impossible to determine the HIV status of a woman in labor deemed to be at high risk for HIV infection, due to patient refusal, absence, or other factors, and the mother refuses HIV testing for her newborn, then the Department of Children and Family Services (DCFS) should be petitioned for authorization to perform a rapid HIV test on her baby, once born, to determine whether or not preventive antiretroviral treatment is indicated in her baby. It should of course be followed up with a confirmatory Western Blot.
 - h) As with the mother, treatment for neonates who test HIV positive should be given to prevent transmission (see Procedures for Newborn below) even though a confirmatory test result may not be available yet. Note that a positive test in the baby is due to the presence of maternal IgG antibody, and thus is indicative of HIV infection in the mother, but not necessarily in the baby. It does indicate that the baby is at risk for mother to child HIV transmission (MTCT), as thus should receive preventive antiretroviral therapy as soon as possible. With DCFS authorization, the baby can then be managed in the same way as other babies at risk for MTCT.

How to Order a Rapid Test

- a) Obtain patient consent on standard HIV testing form
- b) Current LAC+USC Medical Center protocol requires that three signatures appear on the HIV test requisition, the signature of the patient, the signature of the ordering physician, and the signature of a witness
- c) **HAND WRITE** "Rapid HIV Test" on the HIV requisition form

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- d) Provide telephone number, pager, and legible name of clinician ordering the test on the test requisition.
- e) Attach an Expedited Handling Form to the HIV testing form to ensure STAT handling.
- f) Telephone Core Laboratory at 323-226-7039 to notify of request
- g) Hand-deliver to either GH 2309A (Lab Distribution Center) or WCH 1M3 (TRAM station)
- h) Specimen requirements are:

Test	No./type of tube	Deliver to:
Rapid HIV Test: For mother:	1 full Gold Gel	Hand Deliver to GH 2309 (Lab Distribution Center)
For neonate:	1 full Gold Gel (bullet) microcontainer	

- i) Reporting of Results:

The Laboratory will enter the results into the Affinity system and **telephone the results** to the clinician who ordered the test at the number provided on the requisition as soon as the test is completed. If the ordering physician is not available to take the results, the laboratory will contact Dr. Stek (213-209-7354) if the patient is a woman or the MCA physician on call (323-226-2200 or 866-278-6989) if the patient is a baby.

Consultation with MCA staff physicians is essential

All questions that arise as to perinatal and postnatal management with respect to HIV infection of a baby born (or being born) to an HIV-infected, or possibly infected, mother should be referred to the MCA pediatrician on call for neonatal issues. Maternal management should be discussed with Dr. Stek (213-209-7354) or, if she is unavailable, with another MCA physician (323-226-2200 or 866-278-6989).

Maternal Post-partum Care

Human immunodeficiency virus is present in the breast milk of HIV-infected women. Because of the significant risk of vertical transmission of HIV through breast-feeding, women with known or suspected HIV infection should be instructed not to breast feed.

Postpartum management is discussed with all pregnant women in the MCA clinic, and a plan will generally have been formulated prior to delivery.

Code 45 Guidelines: Overview and Treatment Recommendations (cont)

If the woman was on anti-retroviral medications prior to pregnancy, these should be resumed as soon as possible after delivery. Some women, however, may elect to discontinue anti-retroviral treatment post-partum.

Some women with higher baseline CD4 counts and lower viral loads are on antiretroviral therapy only to prevent mother-to-child transmission; these women should discontinue antiretrovirals immediately postpartum.

All follow-up, including wound care, post-partum visits, contraception, colposcopy, and HIV care, can be done at the MCA Clinic. Most women should be seen at the MCA Clinic approximately 2 weeks post-partum.

If the woman received intrapartum single-dose nevirapine and no postpartum antiretroviral treatment, she is at risk of developing HIV mutations conferring resistance to nevirapine. Additional antiretroviral treatment, such as zidovudine + lamivudine for 3 weeks postpartum is likely to decrease this risk and consultation with MCA staff physicians is essential.

Natural History Study

The MCA Center administers a research study known as the Natural History Study. The goal of this study is to longitudinally evaluate HIV-infected women and their infants, in order to characterize the long-term consequences of HIV infection, *in utero* exposure to HIV, and exposure to anti-HIV therapy in the presence or absence of other infections. All HIV-infected pregnant women referred to the MCA Center for medical care are eligible for recruitment. An MCA Research Nurse describes the study to them, and if they agree, informed consent is obtained.

Procedures for Labor, Delivery, and Newborn Specimen Collection

The following pages describe the procedures for the Labor and Delivery Nursing Staff, the Neonatal Intensive Care Unit, and the MCA Program Research Nursing Staff. The specimens to be collected are: labor blood, cord blood, placenta, baby day 1 blood, and blood and urine specimens from baby prior to discharge.

For women who consent, in addition to blood specimens drawn as part of routine care for Code 45 women, blood is drawn for research purposes. Some patients will be enrolled in other research studies and protocol-specific procedures will be carried out by research staff.

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Procedures for Labor and Delivery Nursing Staff

1. Contact Dr. Alice Stek (213) 209-7354 and Research RN (213) 717-3884. If Dr. Stek is not available, contact the OB on-call staff member and the MCA physician on call. If the patient is a non-confirmed but suspected Code 45 patient, contact Dr. Stek and the MCA physician on call. The on-call MCA physician can be contacted by calling the MCA Program 24-hour telephone number (323-226-2200 or 866-278-6989). If this is not successful, call the providers listed on the first page of this protocol. As a last resort, call the Pediatric Emergency Room (323-226-3601).
2. Obtain prenatal care records from the “Code 45” file in the medicine room on 5L, labor and delivery, punch holes in these prenatal records and place them in the mother’s hospital chart, so they will be easily available for the obstetricians, pediatricians and any consultants. Women’s and Children’s Hospital (WCH) Medical Records office also has copies of the prenatal care records. The “OB folder” at WCH Medical Records contains copies of the MCA Clinic records. Please do not call the MCA Clinic for the records.
3. Obtain the following **maternal labor blood specimens**: (Packages of appropriate tubes are stored in the 5L medicine room).

Labor Blood Specimens

Test	No./type of tube	Volume drawn	Deliver to
CBC with differential, if not already drawn on patient	1 purple	2 cc	Central Receiving
Comprehensive metabolic panel (SMAC)	1 gold gel	2 cc	
T&B lymphocyte subset panel (if new patient)	1 purple	2 cc	
HIV RNA PCR (viral load)	1 purple	2 cc	
If new patient: Hepatitis A Total Hepatitis B (HbsAg) Hepatitis C (HCVAb)	1 gold gel	1.5 cc	
Syphilis serology (RPR) (if new patient)	1 gold gel	1cc	
TORCH (if new patient)	1 gold gel	2 cc	
Storage (if Natural History Study participant)*	1 yellow ACD 1 purple	10 cc 10 cc	Hold for pick-up by MCA staff

* Label the tubes with mother’s name and PF number. Place all tubes in a plastic bag and place in the unplugged MCA Research storage cabinet located on 5-M of the Delivery Surgical Suite. These specimens must NOT be refrigerated. Page Research RN (213) 717-3884 for pick-up.

Procedures for Labor and Delivery Nursing/Staff (cont)

4. Start IV line for ZDV (AZT, Retrovir) infusion after the physician has written the order. A separate IV line will need to be started for any additional medication, such as oxytocin. Patients who have not been on anti-HIV medication and/or those at increased risk for vertical transmission, may have additional anti-HIV medication ordered, at the discretion of the physician in consultation with Dr. Stek or another MCA physician.
5. Loading dose of ZDV (AZT, Retrovir) is 2 mg/kg to infuse over 1 hour. Then, maintenance dose of ZDV is 1 mg/kg/hr to infuse continuously throughout labor and delivery.
6. Continue patient's other oral antiretroviral medication, except stavudine (d4T, Zerit), during labor.
7. Document in L&D nursing notes the following: onset of labor, rupture of membranes, number of cervical exams and time performed, and start/stop times of anti-retroviral therapy and other medications.
8. Ensure that package of cord blood tubes is at patient's bedside.
9. All Code 45 babies should be transferred to the NICU for further evaluation.

If there are any questions about what needs to be done with the labor blood specimens, please contact Dr. Stek (213-209-7354) or other physicians listed in (1) above.

Cord Blood Specimens

1. Obtain the following **cord blood specimens**:

Test	No./type of tube	Volume drawn
TORCH IgM and IgG	1 gold gel	1-2 cc
Syphilis serology (RPR) (if mother is RPR positive)	1 gold gel	1-2 cc
Storage (If Natural History Study participant)	1 yellow ACD	5 cc
	1 purple	5 cc

Procedures for Labor and Delivery Nursing/Staff (cont)

2. Label the tubes with the mother's name and PF number. Put all tubes in a plastic bag and place in the unplugged MCA Research refrigerator located on 5-M.
3. Page Research RN (213) 717-3884 for pick-up of the cord blood.

If there are any questions about what needs to be done with the cord blood specimens, please contact the on-call MCA pediatrician (323-226-2200).

Placenta

1. Bag the **placenta** with formalin and place in plastic container.
2. The physician will need to fill out the requisition to include clinical information, such as anti-retroviral drugs, gestational age, mode of delivery, significant complications of pregnancy, labor and delivery, or baby, if applicable, and the baby's birth weight. Write "CODE 45" on the requisition and attach to container
3. Send the placenta to the Pathology Laboratory.

If there are any questions about what needs to be done with the placenta, please contact Dr. Stek (213-209-7354), or if unavailable, the on-call MCA physician at (323) 226-2200.

Procedures for NICU/Newborn Nursing/Staff

All Code 45 babies should be transferred to the Neonatal Intensive Care Unit (NICU) for further evaluation. When the NICU staff receives the delivery information, please page the Research RN at (213) 717-3884

Baby Day 1 Blood

1. Bathe infant in Hibiclens and water before any medications are given or any blood is drawn.

Procedures for NICU/Newborn Nursing/Staff (cont)

2. Obtain the following specimens:

Test	No./type of tubes	Volume drawn	Deliver to:
Within 4 hours of birth:			
CBC with differential	1 purple (priority)	2 cc	Central Receiving
Comprehensive metabolic panel	1 gold gel (priority)	2 cc	
HIV DNA PCR	1 purple	1-2 cc	
T&B lymphocyte subset panel <small>(if delivery is on Friday or Saturday, draw on Sunday)</small>	1 purple	1-2 cc	
Within 48 hours of birth:			
TORCH IgM and IgG <small>(if not done on cord blood)</small>	1 gold gel	1 cc	Central Receiving
Syphilis serology (RPR) <small>(if mother is RPR positive and not done on cord blood)</small>	1 gold gel	1cc	
Storage (If Natural History Consent Form signed)	1 yellow ACD	2-5 cc	Hold for pick-up by MCA staff
	1 purple	2-5 cc	

3. Send tubes for CBC, TPN panel, HIV DNA PCR, and T and B lymphocyte subsets to Central Receiving within 4 hours of birth. Tube for TORCH panel and syphilis serology should be drawn and sent to Central Receiving within 48 hours. For the remaining tubes, put all tubes in a plastic bag and place in specimen refrigerator in NICU. Page Research RN at (213) 717-3884 for pick-up.

Procedures for NICU/Newborn Nursing/Staff (cont)

4. Start ZDV (AZT, Retrovir) syrup (50 mg/5 ml) at 2 mg/kg p.o. q. 6 hrs. as soon as possible within the first 6 hours after birth after receiving an order from the physician. Infants whose mother did not receive anti-HIV medication prenatally and/or those infants at high risk for vertical transmission, may have additional anti-HIV medication ordered, at the discretion of the physician in consultation with the pediatric infectious disease/ MCA Clinic physician on call. Babies whose mothers did not receive anti-retroviral therapy (ART) during labor and delivery should receive ZDV and possibly other ART as soon as possible after delivery (within the first 1-2 hours). If the infant is unable to tolerate the ZDV by mouth, begin IV ZDV 1.5 mg/kg every 6 hours. For pre-term infants (estimated gestational age <34 weeks), the dose of ZDV should be reduced (as per 1c in Overview above) after consultation with the pediatric infectious disease/MCA Clinic physician on call (323-226-2200).

5. **Do not allow the mother to breastfeed.**

Prior to discharge

1. Obtain the following samples **on two separate days**:

Test	Type of sample	No./type of tube	Deliver to:
CMV urine culture	Urine	1 yellow no additive	Central Receiving

2. Order ZDV (AZT, Retrovir) syrup (50 mg/5 ml) 2 mg/kg p.o. q. 6 hrs. x 6 weeks from pharmacy.

3. Train the mother to administer the ZDV to the infant and counsel her regarding possible side effects such as anemia, poor feeding, or vomiting.

4. Schedule Maternal Child and Adolescent Clinic appointment prior to discharge: Call (323) 226-2200 or page Research RN at (213) 717-3884, to make an appointment for the baby and the mother to be seen at the MCA Clinic at 14 days of age.

5. The MCA physician will evaluate all babies born to Code 45 mothers prior to discharge.