



September 2018

Dear Colleague:

This letter provides important information related to prevention of mother-to-child transmission (MTCT) of HIV. Issues addressed in the letter are: 1) intrapartum antiretroviral therapy/prophylaxis, 2) neonatal antiretroviral prophylaxis and 3) HIV testing of infants and children less than 24 months of age.

In November 2017, the U.S. Department of Health and Human Services (DHHS) Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) issued updated Recommendations for Use of Antiretroviral Drugs in Pregnant Women with HIV Infection *and* Interventions to Reduce Perinatal HIV Transmission in the United States. Among the updated recommendations were changes related to the administration of antiretroviral medication to HIV-positive women during labor/delivery and to HIV-exposed newborns.

1) INTRAPARTUM ANTIRETROVIRAL THERAPY/PROPHYLAXIS

Previous DHHS guidelines and the current New York State Department of Health (NYSDOH) AIDS Institute Clinical Guidelines Program perinatal guidelines recommend administration of intrapartum intravenous zidovudine (IV ZDV) for women who have an HIV RNA viral load of >1,000 copies/mL late in pregnancy/close to delivery or whose viral load is not known at delivery. This recommendation also applies to women who were not able to tolerate or adhere to their antiretroviral therapy regimen during the antepartum period.

In the November 2017 update, the Panel recommended that, in addition to the above criteria: **“Intrapartum IV ZDV should be considered for women with HIV RNA between 50 and 999 copies/mL. The transmission risk is slightly higher (approximately 1% to 2%) when HIV RNA is in the range of 50 to 999 copies/mL compared to <50 copies/mL (1% or less).”** Please see **Attachment 1** for more detail on this new recommendation.

Given the relative safety of administering intrapartum (IP) IV ZDV and significant benefit in preventing MTCT, the NYSDOH concurs and supports the updated DHHS recommendation to administer IP IV ZDV in women with HIV who have HIV RNA levels of 50 to 999 copies/mL.

The NYSDOH AIDS Institute Clinical Guidelines Program committee is currently reviewing the present NYS guidelines. The NYS guidelines will be fully aligned with those of DHHS on this important issue. When they are updated, you will be notified. In the interim, birth facilities are encouraged to administer IP IV ZDV when a woman’s HIV RNA is 50 or more copies/mL, per the DHHS guidelines.

2) NEONATAL ANTIRETROVIRAL PROPHYLAXIS

The November 2017 update to the DHHS guidelines included significant revisions to the recommendations for administration of antiretroviral prophylaxis to HIV-exposed newborns. Specifically, the DHHS guidelines now recommend initiation of empiric treatment for HIV with combination antiretroviral therapy for newborns at highest risk for HIV acquisition.

<https://aidsinfo.nih.gov/guidelines/html/3/perinatal/187/antiretroviral-management-of-newborns-with-perinatal-hiv-exposure-or-perinatal-hiv>

The NYSDOH AIDS Institute Clinical Guidelines Program committee is reviewing the NYS neonatal guidelines. When the guidelines are fully updated, you will be notified. In the interim, clinicians providing care to newborns at high risk of HIV acquisition are advised to consult with a pediatrician experienced with treatment of HIV in infants regarding administration of HIV prophylaxis and the choice of antiretroviral medications for high-risk newborns. Care providers with limited access to an HIV experienced pediatrician are advised to consult with the Clinician Consultation Center by calling the Perinatal HIV Hotline at (888) 448-8765. The hotline is operational 24 hours, seven days a week.

3) HIV TESTING OF INFANTS AND CHILDREN LESS THAN 24 MONTHS OF AGE

The NYSDOH is aware of an issue being encountered by some NYS providers and clinical laboratories related to HIV testing of young children, including that there are age restrictions associated with most HIV diagnostic tests and the need for updated recommendations for HIV diagnostic testing of infants and young children. The NYSDOH's Wadsworth Center is working with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to address these issues.

Although within the recommended CDC Laboratory HIV Testing Algorithm, most of the FDA-approved HIV diagnostic tests restrict their use to individuals 2 years of age or older, the NYSDOH is aware that the INSTI HIV-1/HIV-2 Antibody Test (bioLytical Laboratories Inc.) package insert does not include any age-related restrictions or limitations. Therefore, laboratories may perform the INSTI HIV-1/HIV-2 Antibody Test to screen for HIV antibodies in the appropriate specimens regardless of the patient's age.

INSTI is a rapid test kit approved by the FDA for the detection of HIV-1/2 antibodies in venipuncture whole blood, fingerstick blood, or plasma specimens. A reactive result on the INSTI test is interpreted as preliminary positive for HIV antibodies and additional testing must be performed to confirm the presence of HIV infection. If the INSTI test result is reactive for an infant or child under 24 months of age, because maternal HIV antibodies cross the placenta and can persist in the exposed infant for up to 18-24 months, diagnostic testing to confirm or rule out HIV-1 infection must be performed using an HIV-1 nucleic acid test (NAT) which directly detects virus in the infant's blood.

In HIV-exposed infants, serial diagnostic testing over several months is needed to rule out infection. NYS recommends collecting a specimen for diagnostic testing of known HIV-exposed infants within 48 hours of birth, at 2 weeks of age, at 4-6 weeks of age, and at 4-6 months of age. The Wadsworth Center's Pediatric HIV Testing Service conducts diagnostic testing free of charge for all HIV-exposed infants in NYS. NYS providers are encouraged to use this service.

For information, call the Bloodborne Viruses Laboratory at (518) 474-2163 or go to <https://www.wadsworth.org/programs/id/bloodborne-viruses/clinical-testing/pediatric-hiv> for more information.

If you have questions about the content of this letter or would like to discuss anything related to the letter, please contact the Perinatal HIV Prevention Program at (518) 486-6048 or email phpp@health.ny.gov

Thank you for your ongoing commitment to caring for women living with HIV and their infants. Your efforts have been extremely successful, as evidenced by the fact that NYS is close to “eliminating” mother-to-child transmission of HIV.

Sincerely,

Charles John Gonzalez, MD
Medical Director
AIDS Institute

INTRAPARTUM INTRAVENOUS ZIDOVUDINE

The November 2017 update to the federal Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection *and* Interventions to Reduce Perinatal HIV Transmission in the United States provide a new recommendation for when intrapartum intravenous zidovudine should be considered for administration.

Per these updated guidelines:

Page D-1 (yellow highlighting indicates new language and references):

“Intravenous (IV) zidovudine:

- Should be administered to women living with HIV with HIV RNA >1000 copies/mL (or unknown HIV RNA) near delivery **(AI)**.
- Is not required for women receiving antiretroviral therapy (ART) regimens who have HIV RNA ≤ 50 copies/mL during late pregnancy and near delivery and have no concerns regarding adherence to the ART regimen **(BII)**.
- May be considered for women with HIV RNA between 50 and 999 copies/mL. There are inadequate data to determine whether administration of IV zidovudine to women with HIV RNA levels between 50 and 999 copies/mL provides any additional protection against perinatal transmission. However, some experts would administer IV zidovudine to women with RNA levels in this range, as the transmission risk is slightly higher when HIV RNA is in the range of 50 and 999 copies/mL compared to <50 copies/mL **(CII)**.”

Page D-2:

Many experts “recommend intrapartum IV zidovudine administration to women with RNA levels in this range, as the transmission risk is slightly higher (approximately 1%-2%) when HIV RNA is in the range of 50 to 999 copies/mL compared to <50 copies/mL (1% or less).^{1, 5, 6}”

References 1, 4, 5 and 6:

1. Briand N, Warszawski J, Mandelbrot L, et al. Is intrapartum intravenous zidovudine for prevention of mother-to-child HIV-1 transmission still useful in the combination antiretroviral therapy era? *Clin Infect Dis*. 2013;57(6):930-914. Available at <http://www.ncbi.nlm.nih.gov/pubmed/23728147>.
4. Wong VV. Is peripartum zidovudine absolutely necessary for patients with a viral load less than 1,000 copies/ml? *J Obstet Gynaecol*. 2011;31(8):740-742. Available at <http://www.ncbi.nlm.nih.gov/pubmed/22085066>
5. Townsend CL, Byrne L, Cortina-Borja M, et al. Earlier initiation of ART and further decline in mother-to-child HIV transmission rates, 2000-2011. *AIDS*. 2014;28(7):1049-1057. Available at <http://www.ncbi.nlm.nih.gov/pubmed/24566097>
6. Myer L, Phillips TK, McIntyre JA, et al. HIV viraemia and mother-to-child transmission risk after antiretroviral therapy initiation in pregnancy in Cape Town, South Africa. *HIV Med*. 2017;18(2):80-88. Available at <https://www.ncbi.nlm.nih.gov/pubmed/27353189>