



## Table of Contents

Performance Measure: Diagnostic Testing to Exclude HIV Infection in Exposed Infants.....	2
Performance Measure: Neonatal Zidovudine Prophylaxis .....	5
Performance Measure: PCP Prophylaxis for HIV Exposed Infants .....	8



**Performance Measure: Diagnostic Testing to Exclude HIV Infection in Exposed Infants**

**National Quality Forum #: None**

**Description:** Percentage of exposed infants<sup>1</sup> born to HIV-infected women who received recommended virologic diagnostic testing<sup>2</sup> for exclusion of HIV infection in the measurement year

**Numerator:** Number of HIV-perinatally exposed infants who had at least two virologic diagnostic tests performed at appropriate time points<sup>2</sup> by age of six months to definitively exclude HIV infection

**Denominator:** Number of HIV-perinatally exposed infants who

- Were 6-12 months of age at any point in the measurement year; And
- Who had a medical visit with a provider with prescribing privileges<sup>3</sup> at least once in the measurement year

**Patient Exclusions:**

- Patients who were newly enrolled after six months of age
- Patients diagnosed with HIV infection

**Data Elements:**

1. Was the patient 6-12 months of age at any point in the measurement year? (Y/N)
  - a. If yes, was the infant born to an HIV-infected woman? (Y/N)
    - i. If yes, was the patient seen by a provider with prescribing privileges during the measurement year? (Y/N)
      1. If yes, did the infant have documentation of receiving at least two virologic diagnostic tests at recommended time points<sup>2</sup> to definitively exclude HIV infection? (Y/N)
        - a. If yes, list dates.

**Data Sources:**

- Electronic Medical Record/Electronic Health Record
- CAREWare, Lab Tracker or other electronic database
- Medical record data abstraction by grantee of the sample records
- Billing Records

**National Goals, Targets, or Benchmarks for Comparison: None**

**Outcome Measures for Consideration:**

- Median age of diagnosis of HIV infection
- Median age of exclusion of HIV infection
- Rate of opportunistic infections among clinic population

**Basis for Selection:**

HIV virologic testing should be performed at a minimum at ages 14 to 21 days, 1 to 2 months and 4 to 6 months of age.

Antibiotic prophylaxis against PCP is recommended for infants with indeterminate HIV infection starting at 4-6 weeks of life or until they are determined to be uninfected. Diagnostic testing allows PCP prophylaxis to be avoided or stopped if confirmed uninfected.<sup>4</sup>

**U.S. Department of Health & Human Services Guidelines:**

- Virologic assays that directly detect HIV must be used to diagnose HIV in infants and children aged <18months with perinatal and postnatal HIV exposure; HIV antibody tests should not be used (All).
- HIV RNA or HIV DNA NATs are generally equally recommended (All)
- An assay that detects HIV non-B subtype viruses or Group O infections is recommended for use in infants and children who were born to mothers with known or suspected non-subtype virus or Group O infections (All).
- Virologic diagnostic testing is recommended for all infants with perinatal HIV exposure at the following ages:
  - 14 to 21 days (All)
  - 1 to 2 months (All)
  - 4 to 6 months (All)
- For infants at higher risk of perinatal HIV transmission, additional virologic diagnostic testing is recommended at birth (All) and at 2 to 4 weeks after cessation of antiretroviral prophylaxis (BII)
- A positive virologic test should be confirmed as soon as possible by a repeat virologic test on a second specimen (All)
- Definitive exclusion of HIV infection in nonbreastfed infants is based on two or more negative virologic tests, with one obtained at age  $\geq 1$  month and one at age  $\geq 4$  months, or two negative HIV antibody tests from separate specimens obtained at age  $\geq 6$  months (All)
- Some experts confirm the absence of HIV at 12 to 18 months of age in children with prior negative virologic tests by performing an HIV antibody test to document loss of maternal HIV antibodies (BIII)
- Since children aged 18 to 24 months with perinatal HIV exposure occasionally have residual maternal HIV antibodies, definitive exclusion or confirmation of HIV infection in children in this age group who are HIV antibody-positive should be based on an HIV NAT (All)
- Diagnostic testing in children with nonperinatal exposure only or children with perinatal exposure >24 months relies primarily on the use of HIV antibody tests; when acute HIV infection is suspected, additional testing with an HIV NAT may be necessary to diagnose HIV (All)



## References/Notes:

- <sup>1</sup> For the purposes of this measure “infants” includes all patients 6 to 12 months of age.
- <sup>2</sup> Definitive exclusion of HIV infection in non-breastfed infants is based on 2 or more negative virologic test, with 1 obtained at age  $\geq$  1 month and 1 at age  $\geq$ 4 months, or 2 or negative HIV antibody tests from separate specimens obtained at age  $\geq$ 6 months (All).
- <sup>3</sup> A “provider with prescribing privileges” is a health care professional who is certified in his/her jurisdiction to prescribe medications.
- <sup>4</sup> Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. [Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection](#). Available online. Accessed January 2019. Section C-1.



**Performance Measure: Neonatal Zidovudine Prophylaxis**

**National Quality Forum #:** None

**Description:** Percentage of infants <sup>1</sup> born to HIV-infected women who were prescribed ZDV prophylaxis<sup>2</sup> for HIV within 12 hours of birth during the measurement year

**Numerator:** Number of infants born to HIV-infected women who were prescribed ZDV prophylaxis within 12 hours of birth during the measurement year

**Denominator:**

Number of infants who:

- Were born to HIV-infected women during the measurement year; and
- Had a visit with a provider with prescribing privileges<sup>3</sup> in an HIV setting <sup>4</sup> during the measurement year

**Patient Exclusions:** None available at this time

**Data Elements:**

1. Was the infant born to an HIV-infected woman during the measurement year? (Y/N)
  - a. If yes, was the infant seen by a provider with prescribing privileges in an HIV setting during the measurement year? (Y/N)
    - i. If yes, was ZDV prophylaxis prescribed within 12 hours of (Y/N)
      1. If yes, list the date.

**Data Sources:**

- Electronic Medical Record/Electronic Health Record
- CAREWare, Lab Tracker or other electronic data base
- Medical record data abstraction by grantee of a sample of records
- Billing records

**National Goals, Targets, or Benchmarks for Comparison:** None available at this time

**Outcome Measures for Consideration:** Rate of perinatal transmission

**Basis for Selection:**<sup>5</sup>

Zidovudine was shown in the PACTG 076 study to effectively reduce perinatal HIV transmission and is recommended for all neonates born to mothers with HIV infection. In the PACTGG 076 study, zidovudine alone was shown to effectively reduce perinatal HIV transmission and is



recommended as prophylaxis for neonates whose mothers received ART that resulted in consistent virologic suppression during pregnancy. Page 185 of guideline.

All HIV-exposed infants should receive postpartum antiretroviral (ARV) drugs to reduce perinatal transmission of HIV. The most important contributors to the risk of HIV transmission to an HIV-exposed infant are whether the mother has received antepartum/intrapartum antiretroviral therapy (ART) and her viral load; the risk of transmission is increased if maternal antepartum/intrapartum treatment was incomplete or not received and if maternal viral load is detectable, particularly if it is very high. There is a spectrum of transmission risk that depends on these and other maternal and infant factors, including mode of delivery, gestational age at delivery and maternal health status. In all situations, infant prophylaxis should be initiated as soon as possible after delivery. The interval during which infant prophylaxis can be initiated and still be of benefit is undefined; however, most studies support providing prophylaxis as early as possible after delivery.

#### **US Public Health Guidelines:** <sup>5</sup>

- All HIV-exposed infants should receive postpartum antiretroviral (ARV) drugs to reduce the risk of perinatal transmission of HIV (AI). All newborns perinatally exposed to HIV should receive antiretroviral (ARV) drugs to reduce the risk of perinatal transmission of HIV (AI)
- Infant ARV prophylaxis—at gestational age-appropriate doses—should be initiated as close to the time of birth as possible, preferably within 6 to 12 hours of delivery (AII). Newborn ARV regimens-at gestational age appropriate doses- should be initiated as close to the time of birth as possible, preferably within 6 to 12 hours of delivery (AII)
- A 4-week neonatal zidovudine prophylaxis regimen can be used for full-term infants when the mother has received a standard antiretroviral therapy regimen (ART) during pregnancy with sustained viral suppression and there are no concerns related to maternal adherence (BII). Otherwise, a 6-week course as part of a combination infant prophylaxis regimen is recommended (AI).
- The National Perinatal HIV Hotline (1-888-448-8765) is a federally funded service providing free clinical consultation for difficult cases to providers caring for HIV-infected pregnant women and their infants, and can provide referral to local or regional pediatric HIV specialists.

#### **References/Notes:**

<sup>1</sup> “Infants” includes all patients aged 12 months and younger.

<sup>2</sup> From the Department of Health and Human Services Guidelines: “Therefore, Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission (the Panel) recommends a 4-week neonatal zidovudine prophylaxis regimen for full-term infants if the mother has received standard ART during pregnancy with sustained viral suppression



(usually defined as confirmed HIV RNA level below the lower limits of detection of an ultrasensitive assay) and there are no concerns related to maternal adherence. In all other cases, the infant should receive a 6-week course of zidovudine as part of a combination infant prophylaxis regimen. Dosing recommendations for zidovudine are available for premature infants and an intravenous preparation is available. Table 9 shows recommended zidovudine dosing based on gestational age, birthweight, and the status of maternal antepartum ARV regimens.” Therefore, the Panel now recommends a 4-week neonatal zidovudine prophylaxis regimen for newborns if the mother received ART during pregnancy with viral suppression at or after 36 weeks gestation, and there are no concerns related to maternal adherence. Dosing recommendations for zidovudine are available for premature newborns and an intravenous preparation is available. Table 9 shows recommended neonatal zidovudine dosing based on gestational age and birthweight.

<sup>3</sup> A “provider with prescribing privileges” is a health care professional who is certified in his/her jurisdiction to prescribe medications.

<sup>4</sup> An HIV care setting is one that received Ryan White HIV/AIDS Program funding to provide HIV care.

<sup>5</sup> Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States.

<https://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf>

Available online. Accessed January 2019.



**Performance Measure: PCP Prophylaxis for HIV Exposed Infants**  
**National Quality Forum #: None**

**Description:** Percentage of eligible infants<sup>1</sup> with HIV-exposure who were prescribed PCP prophylaxis in the measurement year

**Numerator:** Number of HIV-exposed infants who were prescribed PCP prophylaxis during the measurement year

**Denominator:**

Number of HIV-exposed infants:

- In whom HIV infection has not been presumptively excluded<sup>2</sup> by 6 weeks of age;  
And
- Had a medical visit with a provider with prescribing privileges<sup>3</sup> at least once in the measurement year

**Patient Exclusions:** Patients who are diagnosed with HIV infection

**Data Elements:**

1. Was the infant seen by a provider with prescribing privileges during the measurement year? (Y/N)
  - a. Was the infant HIV-exposed (born to an HIV-infected woman)? (Y/N)
    - i. If yes, was the infant  $\geq 6$  weeks of age at any point during the measurement year? (Y/N)
      1. If yes, was HIV presumptively excluded by six weeks of age? (Y/N)
        - a. If no, was the infant prescribed PCP prophylaxis during the measurement year? (Y/N)
          - i. If yes, list the date

**Data Sources:**

- Electronic Medical Record/Electronic Health Record
- CAREWare, Lab Tracker or other electronic database
- Medical record data abstraction by grantee of a sample of records
- Billing records





**National Goals, Targets, or Benchmarks for Comparison:** None available at this time

**Outcome Measures for Consideration:**

- Rate of PCP in the clinic population
- HIV- related mortality rates

**Basis for Selection:**

Infants with indeterminate HIV infection status should receive prophylaxis until they are determined to be HIV-uninfected or presumptively HIV-uninfected (AIII).

**Department of Health and Human Service Guidelines: <sup>2</sup>**

Chemoprophylaxis is highly effective in preventing PCP. Criteria for its use are based on a patient's age and CD4 count or percentage. Prophylaxis is recommended for all HIV-infected children aged  $\geq 6$  years who have CD4 counts  $< 200$  cells/mm<sup>3</sup> or CD4 percentage  $< 15\%$ , for children aged 1 to  $< 6$  years with CD4 counts  $< 500$  cells/mm<sup>3</sup> or CD4 percentage  $< 15\%$ , and for all HIV-infected infants aged  $< 12$  months regardless of CD4 count or percentage (AII). Infants born to HIV-infected mothers should be considered for prophylaxis beginning at 4 to 6 weeks of age.

Infants with indeterminate HIV infection status should receive prophylaxis until they are determined to be definitively HIV-uninfected or presumptively HIV-uninfected (AIII). Prophylaxis is not recommended for infants who meet criteria for being definitively or presumptively HIV-uninfected.

**References/Notes:**

- 1 "Infants" includes all patients 12 months of age or younger
- 2 Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children. Department of Health and Human Services [https://aidsinfo.nih.gov/contentfiles/lvguidelines/oi\\_guidelines\\_pediatrics.pdf](https://aidsinfo.nih.gov/contentfiles/lvguidelines/oi_guidelines_pediatrics.pdf). Available online. Accessed January 2019. W-1, W-4 and W-15.
- 3 A "provider with prescribing privileges" is a health care professional who is certified in his/her jurisdiction to prescribe medications.

**Accessibility:** If you need an alternative means of access to any information above, please contact us at [HRSABRWHAPQuality@hrsa.gov](mailto:HRSABRWHAPQuality@hrsa.gov). Please let us know the nature of your accessibility problem and the Web address of the requested information.