

BEYOND THE DIAGNOSIS: A CASE-BASED APPROACH TO CARING FOR THE HIV-EXPOSED NEONATE

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DISCLOSURES

- I, Jennifer Fitzgerald DNP, NNP-BC, have no relevant financial relationships with any commercial interests to disclose.

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OBJECTIVES

- At the conclusion of this presentation the learner will be able to:
 - Describe the impact of perinatal HIV exposure on the fetus/neonate
 - Classify HIV medications used in the treatment of neonates
 - Use knowledge of pharmacodynamics, pharmacokinetics, and exposure risk when considering neonatal HIV drug selection
 - Apply knowledge to two case studies

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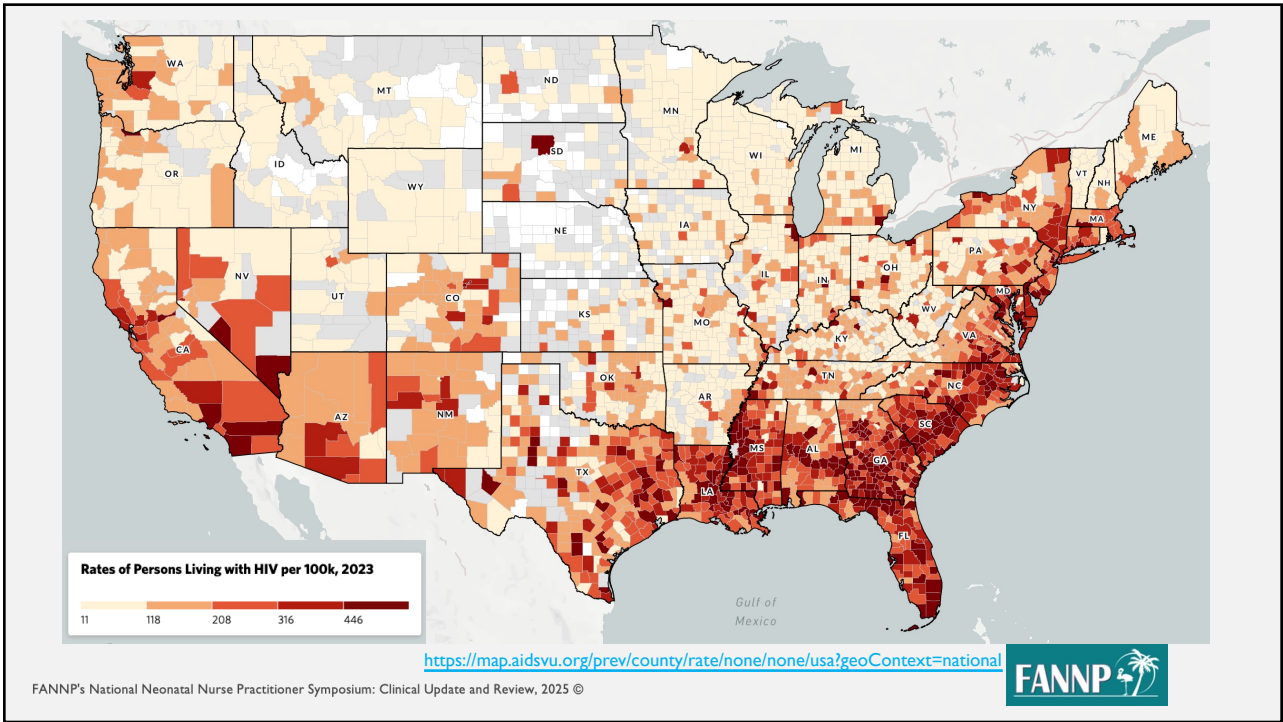
REDUCING PERINATAL HIV TRANSMISSION

- WHO reports a global decline in pediatric cases by 62% since 2010 (2010-2024)
 - Of all people with HIV→87% were aware of status, 77% were receiving ART, and 73% had achieved viral load suppression
 - Of children with HIV globally 55% are on ART
 - United Nations has set target goals of 95-95-95 to be achieved by 2030

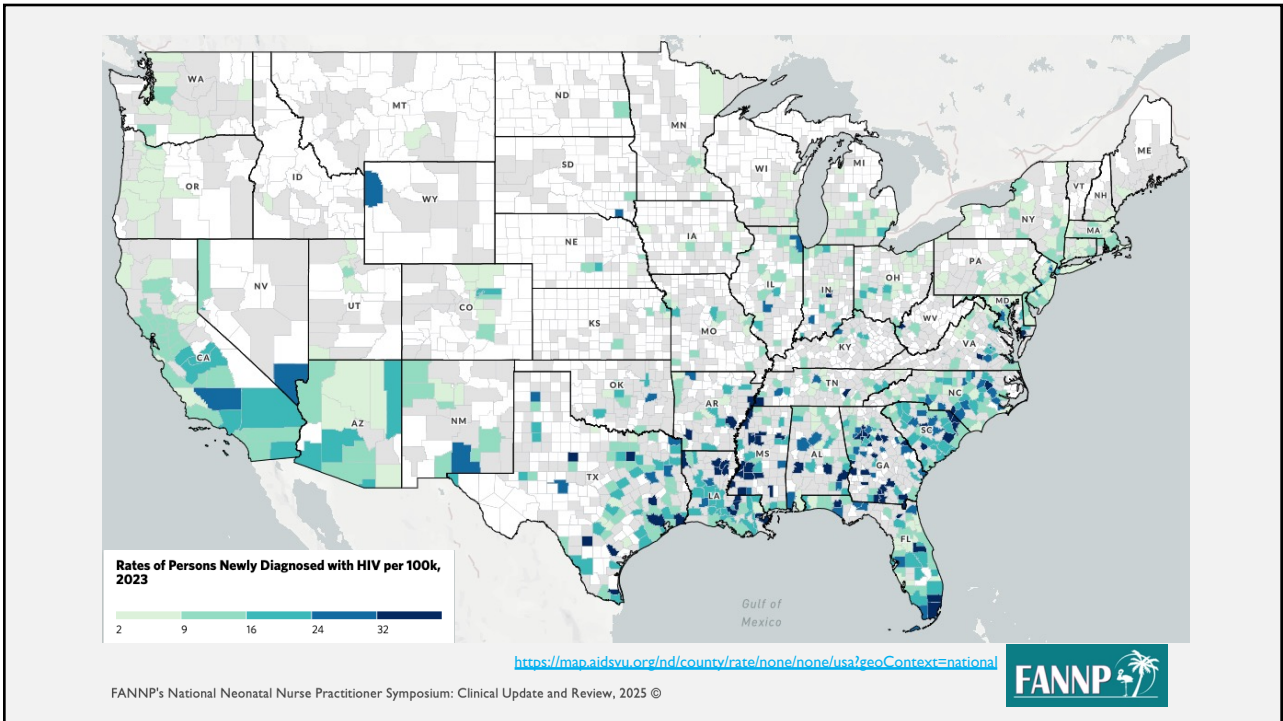
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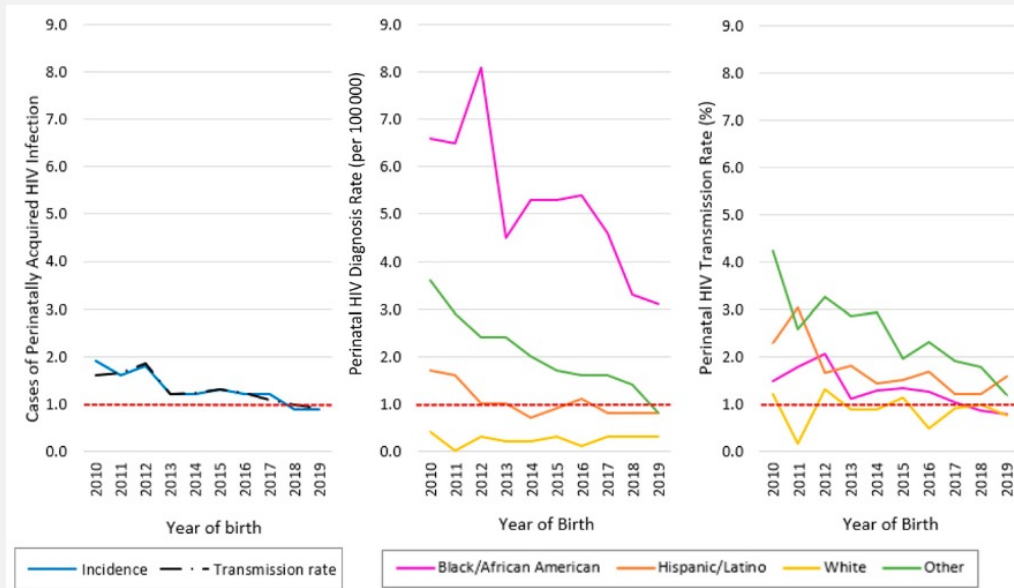
REDUCING PERINATAL HIV TRANSMISSION

- Goal: reduce perinatal transmission to <1% and 1 case per 100,000k live births
 - CDC published framework and set goals in 2012
 - Strategies developed to reduced incidence of antenatal and intrapartum transmission included:
 - HIV screening during pregnancy
 - Initiation of ART therapy in newly diagnosed pregnant women
 - Cesarean delivery for women with elevated viral loads
 - Avoidance of breastfeeding for women living with HIV
 - ART therapy for newborns

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Lampe, et. al. (2023)


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CASE #1		
Maternal History	Prenatal Labs	Management--Maternal
<ul style="list-style-type: none"> • 24 y.o. Hispanic female • G2P1001 • Prenatal care initiated at 30 weeks' gestation • Social history: Recently relocated to the area, limited social supports, no family in the area, Urine Tox + for cannabis, denies ETOH and other drug use 	<ul style="list-style-type: none"> • Blood type: A+ • RPR: Non-reactive • GC: +(treated with TOC pending) • Chl: negative • Hep B & Hep C: Non-reactive • HIV: Positive with 4th generation testing confirming HIV-type 1; Viral load at time of confirmatory testing 25,430 copies/mL; CD4 count low-normal (930 cells/mm³) • GBS pending 	<ul style="list-style-type: none"> • ART initiation at time of diagnosis but with delays on starting therapy (started 10 days prior to delivery) • Initiated IV AZT in L&D • Cesarean delivery performed at 35 3/7 weeks due to preterm labor and premature rupture of membranes (6 hrs PTD)


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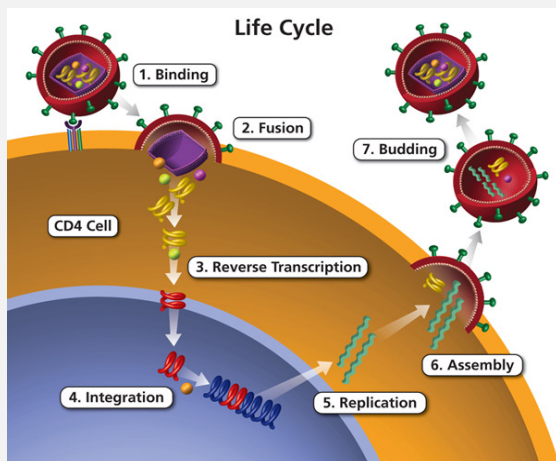
HIV INFECTIONS
<ul style="list-style-type: none"> • Human immunodeficiency virus (HIV) infection caused by one of two viral strains: Type 1 or Type 2 <ul style="list-style-type: none"> • HIV type 1 most prevalent strain in the US • HIV type 2 commonly found in West Africa* • Infect peripheral blood mononuclear cells, brain, bone marrow, & GU tract with transmission noted by blood, human milk, and genital secretions (excluding urine) • Modes of transmission: sexual contact, blood exposure via mucous membranes, sharps/needles, perinatal, & transfusion

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HIV REPLICATION



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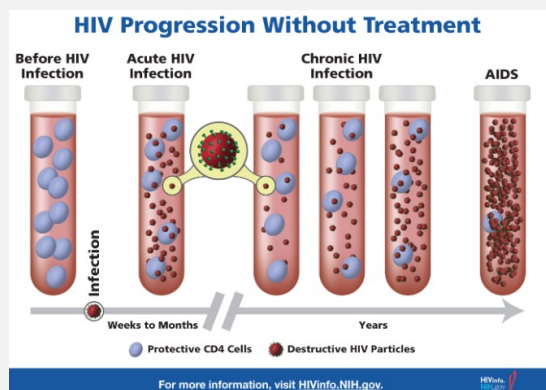
1. HIV virus attaches to CD4 receptor
2. Fusion of virus to cell wall
3. Injection of virus core into cytoplasm of the cell → RT enzyme translates RNA to DNA
4. DNA now in host cell nucleus and incorporated into host genome
5. Steps 5-7 replicates HIV viral DNA creating and releasing more HIV virus



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CLINICAL PRESENTATION

- Adolescents and Adults
 - Staged → specific criteria indicating timing & severity of immune suppression
 - Stage I: First weeks following infection, 40-90% demonstrate:
 - Fever, malaise, lymphadenopathy, & skin rash (known as acute retroviral syndrome) accompanying rapid viral multiplication



For more information, visit HIVinfo.NIH.gov.



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CLINICAL PRESENTATION

- Pediatric
 - Undiagnosed HIV infections present with:
 - Unexplained fevers
 - Lymphadenopathy
 - Hepato/splenomegaly
 - FTT
 - Infections: candidiasis, recurrent bacterial infections, opportunistic infections
 - Severe immune deficiencies/CBC derangements—challenging in the neonate
 - CNS involvement

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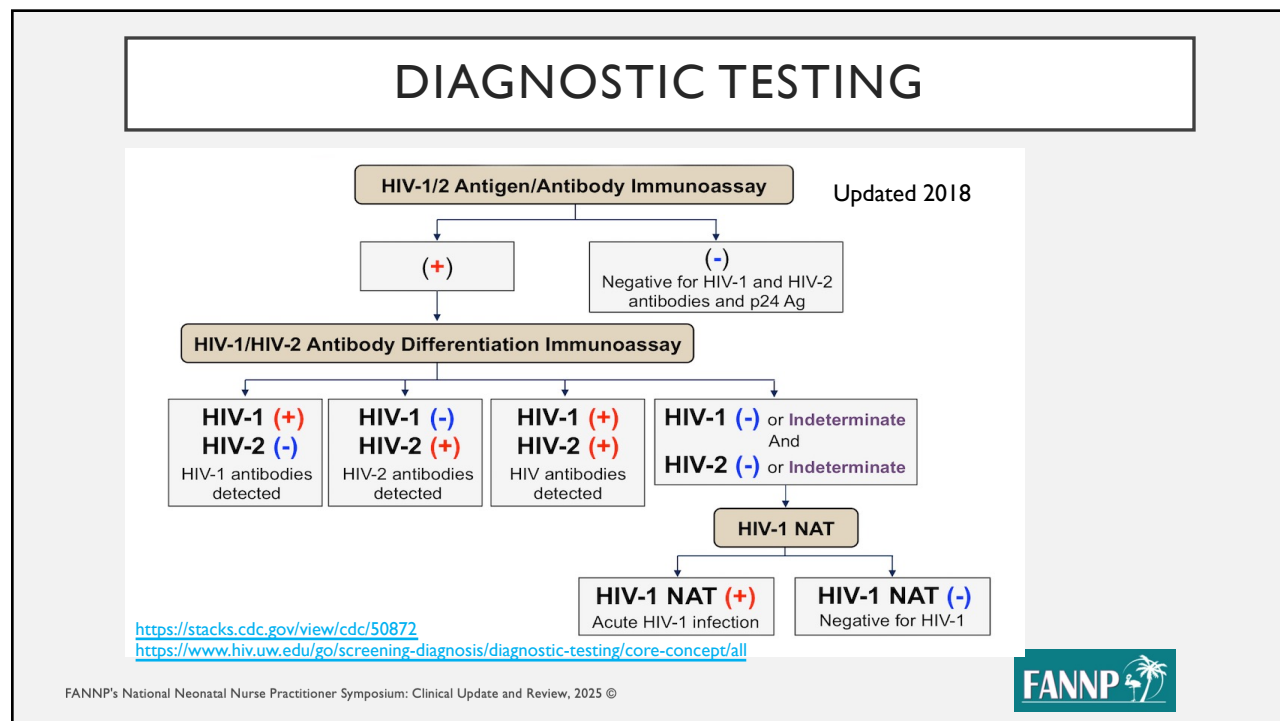
DIAGNOSTIC TESTING

- Who to test?
 - Routine care—discussion with primary care providers
 - Yearly testing for high-risk groups
 - Access to PrEP
 - Risk-based exposures
 - Clinical signs concerning for HIV
 - Prenatal testing
 - Maternal-fetal transmission as high as 24% if untreated
 - *Testing early in 1st trimester and again mid-pregnancy if increased risk
 - Postnatal/Neonatal testing

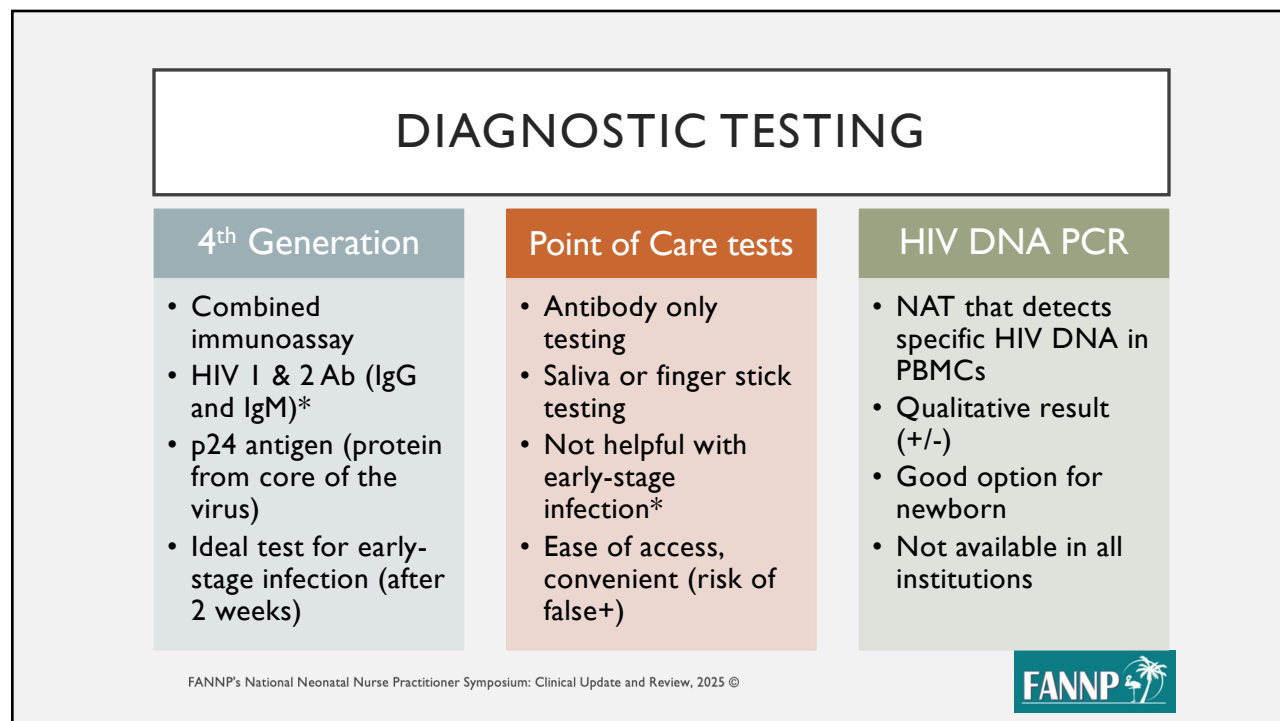
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DIAGNOSTIC TESTING

HIV RNA PCR

- "Viral Load"
- NAT that detects extracellular viral RNA in plasma
- Quantitative result
- Used to detect acute infection and to follow treatment response*
- Recommended for use in newborn exposure testing

CD4 Lymphocyte Count

- Evaluates health of the immune system
- Quantitative result
- Helpful in staging and determining severity of illness
- Helps to understand opportunistic infection risk and need for prophylaxis

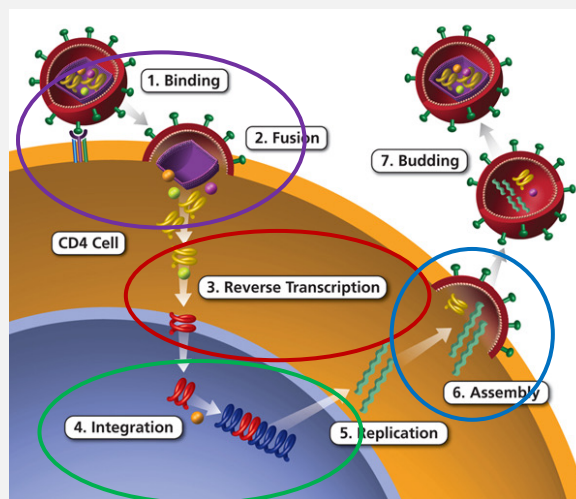
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HIV DRUG CLASSES

- **Nucleoside reverse transcriptase inhibitor (NRTI)**
 - Tenofovir, Zidovudine, Emtricitabine, Lamivudine
- **Non-Nucleoside reverse transcriptase inhibitor (NNRTI)**
 - Doravirine, Efavirenz, Nevirapine
- **Protease Inhibitor (PI)**
 - Darunavir/Ritonavir
- **Integrase Inhibitor (INSTI)**
 - Bictegravir, Dolutegravir, Raltegravir
- **Fusion Inhibitors**



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HIV INFECTION—MATERNAL

- Risk for perinatal transmission as high as 22% in neonates born to women who acquired HIV during pregnancy
- Prompt initiation of ARV plus additional testing to include HIV drug resistance testing
- Maternal ARV therapy options, there are many→therapy often determined by timing of diagnosis and previous exposure to ARV therapy.
 - Preferred ARV in acute HIV*→Bictarvy or Dolutegravir PLUS dual NRTI

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HIV EXPOSURE

- New maternal diagnosis during pregnancy, non-adherence to prescribed ARV therapy or with elevated viral load >1,000 copies/mL→intrapartum
 - Scheduled cesarean is recommended*
 - Intrapartum management with IV Zidovudine→2 mg/kg loading dose over the 1st hour followed by continuous infusion of 1 mg/kg/hr for at least 2 hrs (minimum of 3 hours prior to delivery)

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CASE #1—NEONATE

Resuscitation	Initial labs	Management
<ul style="list-style-type: none">Delivered at 35 3/7 weeksAPGARs: 7¹/9⁵Brought to the NICU for management of TTN and HIV exposurePlaced on CPAP +5 for RR of 80 and FiO2 requirement of 33%	<ul style="list-style-type: none">HIV PCR & CBC testing sent following delivery*LFT's sent for baseline on DOL 1Blood gasAdditional ID testing to be considered if unable to wean from CPAP	<ul style="list-style-type: none">Initiate enteral nutrition via gavage tubeInitiate ARV therapy within 6-12 hoursRepeat testing at 2-3 weeks, 1-2 months, 8-10 weeks, and 4-6 monthsConsideration of Bactrim prophylaxis

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POST-NATAL NEONATAL EVALUATION

- Diagnostic testing:
 - Baseline CBC and LFT's shortly after delivery
 - HIV DNA or RNA PCR testing at the following intervals:

	Birth	2 weeks	3 weeks	4 weeks	8 weeks	12 weeks	4 months	6 months
Low Risk		NAT		NAT			NAT	
High Risk	NAT*	NAT		NAT	NAT*		NAT	

<https://www.hiv.uw.edu/go/screening-diagnosis/ diagnostic-testing/core-concept/all>
[https://publications.aap.org/redbook/book/755/chapter/14078400/Human-Immunodeficiency-Virus-Infection I 10](https://publications.aap.org/redbook/book/755/chapter/14078400/Human-Immunodeficiency-Virus-Infection-I-10)

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PHARMACOLOGIC MANAGEMENT

- Zidovudine (NRTI)
 - Primary drug for neonatal post-exposure prophylaxis and treatment of active infection, initiate within 1 hour of birth (high-risk)
 - MOA: Inhibits RT enzyme activity and blocks RNA→DNA replication; high first-pass metabolism
 - Dosing: Dependent on size and GA
 - <34 ⁶/₇ weeks: 2 mg/kg/dose q12 hours with dose increasing to 3mg/kg/dose q12 hrs between 2-4 weeks PNA*
 - >35 weeks: 4 mg/kg/dose q12 hours for duration of therapy 4-6 weeks
 - IV dosing is a 25% dose reduction with same dosing interval

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PHARMACOLOGIC MANAGEMENT

- Lamivudine (NRTI)
 - Adjunct therapy to be initiated for neonates at high risk of perinatal transmission, presumptive treatment, start in first 6 hours
 - MOA: Inhibits RT enzyme activity and blocks RNA→DNA replication. Synergistic effect with other retrovirals
 - Good oral bioavailability; Clearance improves with PNA
 - Used as part of combination therapy as monotherapy associated with resistance.
 - Dosing: 2 mg/kg/dose enteral BID

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PHARMACOLOGIC MANAGEMENT

- Nevirapine (NNRTI)
 - Adjunct therapy for neonates at high risk of perinatal transmissions; start within first 6 hours
 - MOA: Inhibits RT enzyme activity and blocks RNA→DNA replication without requiring intracellular metabolism. Synergistic effect with Zidovudine.
 - Rapid absorption and quickly metabolized but slow excretion in the neonate, with long $t_{1/2}$ life
 - Dosing: needs close attention to dosing as doses for premature neonate adjust with improving renal function

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PHARMACOLOGIC MANAGEMENT

- Raltegravir (INSTI):
 - For use in neonatal presumptive therapy when concern is high for HIV-2, start within first 6 hours
 - MOA: Blocks integration of HIV DNA into the host CD4 cell. Highly protein bound
 - Dosing: available for neonates >37 weeks and is either weight based or fixed dosing based on weight*
 - Dosing increases with advancing PNA due to maturation of the glucuronidation pathway in the liver

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SIDE EFFECTS OF THERAPY

- Common, known complications of ARV therapy
 - Myelosuppression → anemia and neutropenia, may be profound
 - GI symptoms → emesis, nausea, diarrhea, elevated liver enzymes, elevated bilirubin levels
 - Skin → Rash (esp with Nevirapine)

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ADDITIONAL MANAGEMENT

- Feeding options:
 - For the neonate at *high-risk* of HIV transmission
 - Maternal breast milk discouraged in US
 - Alternatives include donor BM or standard/preterm formula
- Evaluation for opportunistic or co-infections
 - Consideration of CMV, Hepatitis infections, syphilis, toxo and TB
 - Additional imaging if concern for TORCH infections

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CASE #2

Maternal History	Prenatal Labs	Management--Maternal
<ul style="list-style-type: none"> 31 y.o. Black female G3P2002 Prenatal care initiated at 30 Care started in 1st trimester with consistent care throughout pregnancy and undetectable viral loads throughout pregnancy Social history: Married and lives with partner and other 2 children, good family support system, Urine Tox negative, denies ETOH and other drug use 	<ul style="list-style-type: none"> Blood type: O+, neg Ab screen RPR: Non-reactive GC/Chl: negative Hep B & Hep C: Non-reactive GBS negative HIV: Positive, undetectable viral load throughout pregnancy 	<ul style="list-style-type: none"> On combination ART with Bictarvy PNV and Iron supplementation only other meds Spontaneous VD following ROM x3.5 hours

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CASE #1—NEONATE

Resuscitation	Initial labs	Management
<ul style="list-style-type: none"> Delivered at 39 2/7 weeks APGARs: 8¹/9⁵ 3.4 kg BW Admitted to the NBN for newborn care and HIV exposure evaluation 	<ul style="list-style-type: none"> Initial HIV PCR RNA or DNA testing to be sent at 2-3 weeks of age CBC at baseline 	<ul style="list-style-type: none"> Initiate enteral nutrition as tolerated→Mom desires breastfeeding Initiate ARV therapy within 6 hours Repeat testing at 1-2 months, and 4-6 months

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UPDATED FEEDING RECOMMENDATIONS

- New guidance in 2024 highlights benefits to both mom and baby for breastfeeding
 - Need regular and frequent counseling throughout pregnancy on risk of transmission with breastfeeding*
 - Counseling should include that donor milk or formula are only methods of eliminating post-natal HIV exposure
 - No known toxicity from maternal ARV therapy; Hales classifications for this case would be L3
 - Conditions with increased risk of transmission: mixed feeding, mastitis, and thrush

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MANAGEMENT RECOMMENDATIONS

- Viral load testing and breastfeeding
 - Monitored periodically throughout time breastfeeding ~ every 1-2 months
 - Plan in place if viral load becomes detectable during breastfeeding
- Ongoing ARV following initial prophylaxis—is it necessary?
 - Initial prophylaxis 2 weeks for low-risk transmission and continued VL suppression
 - debated by experts with some recommending full 6 weeks followed by transition to Nevirapine or Lamivudine for duration of time breastfeeding*

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PRIMARY CARE CONSIDERATIONS

- Ensure regular PCP appointments
 - PCP comfortable in management of HIV exposure
 - Link to pediatric HIV specialist
 - Ideally medical home model to address social, emotional, health-care access, and prescription coverage
 - Ongoing testing
- Assistance with diagnosis disclosure

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PRIMARY CARE CONSIDERATIONS

- Pneumocystis jirovecii pneumonia (PCP) prophylaxis
 - Start at 4-6 weeks unless there is adequate information to exclude HIV infection
- Ongoing testing
 - Nearly all positive infants identified by 2-4 months of age
 - Will be followed until 18 months or unless definitive testing identifies them earlier

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RULING OUT HIV TRANSMISSION

- Infection can be **presumed** to be excluded in non-breastfed infants
 - with 2 or more negative tests (at ≥ 2 and ≥ 4 weeks)
 - One negative NAT (RNA or DNA PCR) test at ≥ 8 weeks
 - One negative antibody test at ≥ 6 months
- **Definitive** exclusion
 - 2 or more negative tests at ≥ 1 month and again at ≥ 4 months or on 2 separate specimens collected at ≥ 6 months
 - Documentation of negative antibody testing between 12-18 months

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IMMUNIZATIONS

- Immunizations
 - Give all early vaccines
 - <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-pediatric-opportunistic-infections/recommended-immunizations-schedule#rv>
- Considerations
 - Increased risk for infections due to compromised immune system
 - Lower response rate to many vaccines
 - Avoid live vaccines in patients with low CD4 counts as increased risk for illness
 - Avoid MMR and Varicella if severely immuno-compromised

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SUMMARY

- Understand Maternal testing and goal of ARV
- Early ARV can prevent transmission
- Open, collaborative relationship with family
- Understand timing of subsequent viral testing and any ongoing monitoring necessary due to ARV therapies

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KNOWLEDGE QUESTIONS

Which of the following strategies is most effective in reducing perinatal HIV transmission according to CDC guidelines?

- a. Routine prenatal HIV screening and timely initiation of ART
- b. Scheduled cesarean delivery for all HIV-positive women
- c. Breastfeeding exclusively for 6 months with maternal ART

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KNOWLEDGE QUESTIONS

HIV replication begins with which of the following steps?

- a. Integration of viral DNA into the host genome
- b. Attachment of HIV to the CD4 receptor on host cells
- c. Translation of viral RNA into proteins in the cytoplasm

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KNOWLEDGE QUESTIONS

Which antiretroviral drug class includes Zidovudine and Lamivudine?

- a. Nucleoside reverse transcriptase inhibitors (NRTIs)
- b. Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
- c. Integrase inhibitors (INSTIs)

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KNOWLEDGE QUESTIONS

According to updated 2024 feeding recommendations, what is the only method to eliminate postnatal HIV transmission risk?

- a. Exclusive breastfeeding with maternal viral load suppression
- b. Use of donor breast milk or infant formula
- c. Mixed feeding with maternal ART

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KNOWLEDGE QUESTIONS

A neonate, born to an HIV-positive mother with a viral load >1,000 copies/mL, is started on Zidovudine, Lamivudine, and Nevirapine within 1 hour of birth. What is the physiologic rationale for initiating triple therapy so early?

- a. To decrease gastrointestinal side effects by combining drugs from different classes
- b. To delay the need for further diagnostic testing in the first 6 months of life
- c. To reduce the risk of perinatal HIV transmission in high-risk infants through synergistic antiviral activity

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Thank you!

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