

What is a Clinical Pathway?



An evidence-based guideline that decreases unnecessary variation and helps promote safe, effective, and consistent patient care.

Objectives of Pathway



- To standardize management to align with national recommendations to prevent or treat HIV in infants exposed to HIV-infected mothers
- To establish a standardized approach for counseling women living with HIV to support them in their decision about choice of infant feeding (mother's own milk, donor milk, or formula)
- To standardize care to align with national recommendations to prevent HIV transmission to infants with mothers living with HIV who choose to breastmilk feed their infants
- To facilitate pediatric Infectious Diseases (ID) outpatient care following the birth hospitalization

Why is Pathway Necessary?



- New 2024 change in guidelines from the NIH and CDC around women living with HIV and breastmilk feeding their infants
- Also a change in guidelines for HIV perinatal transmission
- This pathway integrates both within one single algorithm
- This pathway also helps to facilitate and link pediatric ID outpatient care following infant discharge from the hospital

Setting



- Where will this pathway be used?
 - NICU
 - Well baby nursery
 - Inpatient units if HIV-exposed infant is admitted
 - Outpatient pediatric ID office

Background



- Breastfeeding & HIV transmission rates pre-ARV (antiretroviral therapy):
 - Breastfeeding transmission was ~15-20% in the first 2 years of infant life¹
 - \circ > 1 month of age 0.6% 0.9% per month²
 - Mixed feeding associated with higher
 - Exclusive BF associated with lower rates

American Academy of Pediatrics Benefits of Breastfeeding³:



Child Benefits:

- Improved dental health
- Improved neurodevelopmental outcomes
- Decreased risk of:
 - o Otitis media
 - Respiratory tract infection
 - Necrotizing enterocolitis
 - o SIDS
 - Atopic dermatitis
 - Asthma
 - Celiac disease
 - Inflammatory bowel disease
 - Late-onset sepsis in preterm infants
 - Type 1 and type 2 diabetes
 - Leukemia
 - Childhood overweight and obesity

Maternal Benefits:

- Decreased risk of:
 - Excessive menstrual blood loss
 - Breast, ovarian, endometrial, and thyroid cancers
 - Hypertension
 - Type 2 diabetes
 - Rheumatoid arthritis

Other Influences:



Cultural

 Abstaining from breastfeeding as a means of disclosure

Economic

- Expense of formula
- Access to safe and clean water sources



Literature Review



 Increased maternal ARV adherence was associated with lower breast milk and plasma viral loads

 Higher breast milk and plasma viral loads were associated with increased breast milk transmission



BAN Study⁴

High Income Countries-Case Series



No transmission:

- Toronto 3 infants. Triple therapy through breastfeeding which ranged 9-15 weeks.⁵
- US 10 infants breastfed 1-18 months. Triple therapy through 4-6 weeks, followed by NVP through 6 weeks post breastfeeding.⁶
- US 8 infants breastfed 2 weeks-6 months. Mixed prophylaxis: AZT, NVP, AZT + NVP, AZT, NVP,+ 3TC up to 6 weeks. Maternal viral loads 40 copes/mL or less.⁷
- Italy 13 infants breastfed for mean of 5.4 months. AZT for 4 weeks.⁸
- Germany 30 infants. 25 with optimal viral suppression, 50-70 copies/mL, AZT 2-8 weeks. 5 infants received no prophylaxis. 9

Of note, the approaches to infant prophylaxis ranged from 4 weeks of zidovudine (ZDV) to three-drug ARV regimens for the duration of breastfeeding

Infant Feeding for Individuals With HIV in the United States 10



Panel's Recommendations

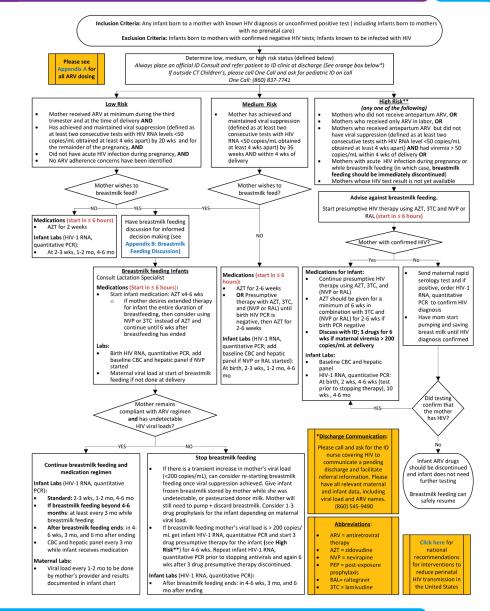
- People with HIV should receive evidence-based, patient-centered counseling to support shared
 decision-making about infant feeding. Counseling about infant feeding should begin prior to
 conception or as early as possible in pregnancy; information about and plans for infant feeding
 should be reviewed throughout pregnancy and again after delivery (AIII). During counseling,
 people should be informed that—
 - Replacement feeding with properly prepared formula or pasteurized donor human milk from a milk bank eliminates the risk of postnatal HIV transmission to the infant (AI).
 - Achieving and maintaining viral suppression through antiretroviral therapy (ART) during pregnancy and postpartum decreases breastfeeding transmission risk to less than 1%, but not zero (AI).

This is the Perinatal HIV Exposure Management (for Breastfeeding and Non-Breastfeeding Newborns) Clinical Pathway.

We will be reviewing each component in the following slides.

CLINICAL PATHWAY: Perinatal HIV Exposure Management (for Breastfeeding and Non-Breastfeeding Newborns)

THIS PATHWAY SERVES AS A GUID AND DOES NOT REPLACE CLINICA JUDGMENT.



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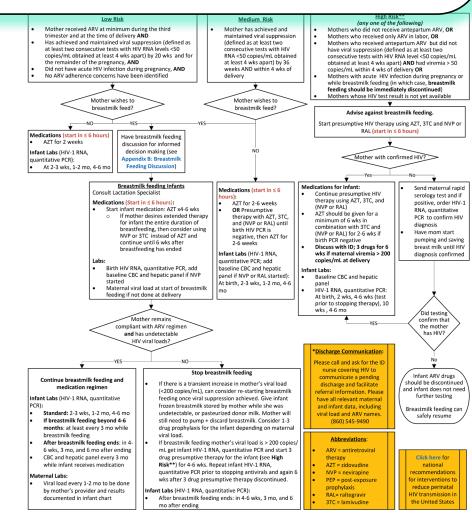
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Inclusion Criteria: Any infant born to a mother with known HIV diagnosis or unconfirmed positive test (including infants born to mothers with no prenatal care)

Exclusion Criteria: Infants born to mothers with confirmed negative HIV tests; Infants known to be infected with HIV

This clinical pathway pertains to any infant born to a mother with known or unconfirmed HIV diagnosis



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Determine low, medium, or high risk status (defined below)

Always place an official ID Consult and refer patient to ID clinic at discharge (See orange box below*)

If outside CT Children's, please call One Call and ask for pediatric ID on call

One Call: (860) 837-7741

Low Risk

- Mother received ARV at minimum during the third trimester and at the time of delivery AND
- Has achieved and maintained viral suppression (defined as at least two consecutive tests with HIV RNA levels <50 copies/mL obtained at least 4 wks apart) by 20 wks and for the remainder of the pregnancy, AND
- Did not have a cute HIV infection during pregnancy, AND
- No ARV adherence concerns have been identified
- The first step in management is to determine the infant's risk status, which is based on mother receiving ARV, achieving/maintaining target viral suppression, and other specific criteria.
- ALWAYS consult Pediatric ID during the newborn hospital admission AND send an outpatient ID referral

High Risk** Medium Risk (any one of the following) Mother has achieved and Mothers who did not receive antepartum ARV. OR maintained viral suppression Mothers who received only ARV in labor. OR (defined as at least two Mothers who received antepartum ARV but did not consecutive tests with HIV have viral suppression (defined as at least two RNA < 50 copies/mL obtained consecutive tests with HIV RNA level <50 copies/mL at least 4 wks apart) by 36 obtained at least 4 wks apart) AND had viremia > 50 weeks AND within 4 wks of copies/mL within 4 wks of delivery **OR** delivery Mothers with acute HIV infection during pregnancy or while breastmilk feeding (in which case, **breastmilk** At 2-3 wks, 1-2 mo, 4-6 mo feeding should be immediately discontinued) Mothers whose HIV test result is not yet available Breastmilk feeding I AZT for 2-6 weeks Start infant medication: AZT x4-6 wks **OR** Presumptive RNA, quantitative AZT should be given for a If mother desires extended therapy therapy with AZT, 3TC, PCR to confirm HIV minimum of 6 wks in for infant the entire duration of and (NVP or RAL) until diagnosis combination with 3TC and breastfeeding, then consider using hirth HIV PCR is (NVP or RAL) for 2-6 wks i Have mom start NVP or 3TC instead of AZT and negative, then AZT for birth PCR negative pumping and saving continue until 6 wks after Discuss with ID: 3 drugs for 6 breast milk until HIV breastfeeding has ended Infant Labs (HIV-1 RNA, wks if maternal viremia > 200 diagnosis confirmed copies/mL at delivery quantitative PCR: add

baseline CBC and hepatic

panel if NVP or RAL started):

At birth, 2-3 wks, 1-2 mo, 4-6

If there is a transient increase in mother's viral load (<200 copies/mL), can consider re-starting breastmilk nfant Labs (HIV-1 RNA, quantitative feeding once viral suppression achieved. Give infant frozen breastmilk stored by mother while she was Standard: 2-3 wks, 1-2 mo, 4-6 mg undetectable, or pasteurized donor milk, Mother will If breastmilk feeding beyond 4-6 still need to pump + discard breastmilk. Consider 1-3 months: at least every 3 mo while drug prophylaxis for the infant depending on materna breastmilk feeding After breastmilk feeding ends: in 4 If breastmilk feeding mother's viral load is > 200 copies, 6 wks, 3 mo, and 6 mo after ending mL get infant HIV-1 RNA, quantitative PCR and start 3

Birth HIV RNA, quantitative PCR, add

Maternal viral load at start of breas

compliant with ARV regime

and has undetectable

feeding if not done at delivery

baseline CBC and hepatic panel if NVP

6 wks, 3 mo, and 6 mo after ending CBC and hepatic panel every 3 mo while infant receives medication while infant receives medication while infant receives medication eternal Labs:

Viral load every 1-2 mo to be done by mother's provider and results documented in infant chart

Infant Labs (HIV-1 RNA, quantitative PCR and start 3 drug presumptive therapy for the infant (see High Risk**) for 4-6 wks. Repeat infant HIV-1 RNA, quantitative PCR and start 3 drug presumptive therapy for the infant chart

Infant Labs (HIV-1 RNA, quantitative PCR and start 3 drug presumptive therapy for the infant chart was a free provided in the provided

O copies/
start 3

ARV = antiretroviri
therapy
AZT = zidovudine
NVP = nevirapine
PEP = post-exposu
prophylaxis
AAL = raltegravir
3TC = lamivudine

nfant Labs

Baseline CBC and hepatic

HIV-1 RNA quantitative PCR

At birth, 2 wks, 4-6 wks (test

prior to stopping therapy), 10 wks , 4-6 mo

**Discharge Communication:
Please call and ask for the ID
nurse covering HIV to
communicate a pending
discharge and facilitate
referral information. Please
have all relevant maternal
and infant does not need
further testing

Did testing

the mother

and infant data, including viral load and ARV names. (860) 545-9490

> Click here for national recommendations for interventions t reduce perinatal HIV transmission i the United States

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- "Low Risk" and "Medium Risk" infants may breastmilk feed if desired by mother
- Providers MUST have a discussion with the mother about the risks and benefits of breastmilk feeding to facilitate informed decision making
- Appendix B outlines the key points of this discussion

CLINICAL PATHWAY:

Perinatal HIV Exposure Management (for Breastfeeding and Non-Breastfeeding Newborns) Appendix B: Informed Discussion for Caregivers Living with HIV and Breastmilk Feeding

There are multiple infant feeding options for those who are born to mother's living with HIV. These include formula feeding, banked donor human milk, and breast "chest" feeding. Based on worldwide data and endorsed by the NIH, the known risk of breastmilk feeding with HIV is not zero but estimated to be < 1%. This risk increases if maternal viral load is not suppressed.

Why parents should consider Breastmilk feeding:

Infant Benefits:

Children who are breastfed experience improved dental health and neurodevelopmental outcomes. They also have decreased risk of:

- Otitis media
- Diarrhea
- Respiratory Tract infection
- Necrotizing enterocolitis
- SIDS
- Atopic dermatitis
- Asthma

CLINICAL PATHWAY: **Perinatal HIV Exposure Management** (for Breastfeeding and Non-Breastfeeding Newborns)

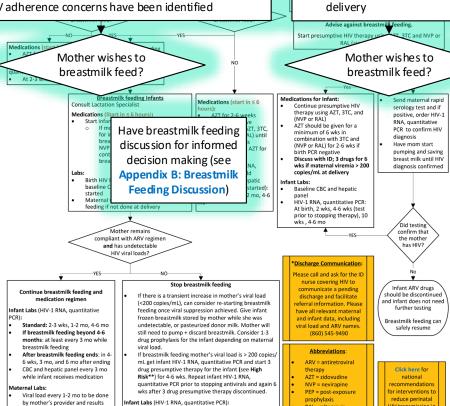
Inclusion Criteria: Any infant born to a mother with known HIV diagnosis or unconfirmed positive test (including infants born to mother with no prenatal care) Exclusion Criteria: Infants born to mothers with confirmed negative HIV tests; Infants known to be infected with HIV

Low Risk

- Mother received ARV at minimum during the third trimester and at the time of delivery AND
- Has achieved and maintained viral suppression (defined as at least two consecutive tests with HIV RNA levels <50 copies/mL obtained at least 4 wks a part) by 20 wks and for the remainder of the pregnancy, AND
- Did not have a cute HIV infection during pregnancy, AND
- No ARV adherence concerns have been identified

Medium Risk

Mother has achieved and maintained viral suppression (defined as at least two consecutive tests with HIV RNA < 50 copies/mL obtained at least 4 wks apart) by 36 weeks AND within 4 wks of deliverv



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After breastmilk feeding ends: in 4-6 wks, 3 mo, and 6



HIV transmission

the United States

RAL= raltegravir

3TC = lamivudine

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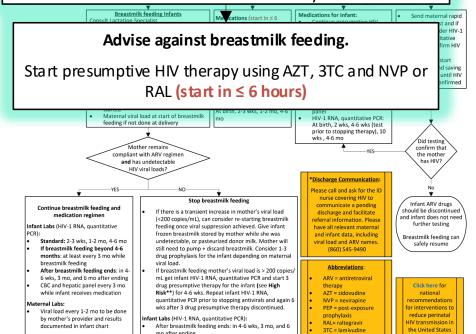
documented in infant chart

 It is inadvisable for "high-risk" infants to breastmilk feed CLINICAL PATHWAY:
Perinatal HIV Exposure Management
(for Breastfeeding and Non-Breastfeeding Newborns)

THIS PATHWAY SERVES AS A GUID AND DOES NOT REPLACE CLINICAL JUDGMENT.

<u>High Risk**</u> (any one of the following)

- Mothers who did not receive antepartum ARV, **OR**
- Mothers who received only ARV in labor, **OR**
- Mothers who received antepartum ARV but did not have viral suppression (defined as at least two consecutive tests with HIV RNA level <50 copies/mL obtained at least 4 wks apart) AND had viremia > 50 copies/mL within 4 wks of delivery OR
- Mothers with acute HIV infection during pregnancy or while breastmilk feeding (in which case, breastmilk feeding should be immediately discontinued)
- Mothers whose HIV test result is not yet available



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Medications (start in ≤ 6 hours)

AZT for 2 weeks

Infant Labs (HIV-1 RNA, quantitative PCR):

At 2-3 wks, 1-2 mo, 4-6 mo

- This pathway gives recommendations for ARV
 prophylaxis for BOTH breastmilk feeding and non-breastmilk feeding infants in all categories.
- In all cases, it is imperative to start ARV medications in ≤ 6 hours from birth
- Medication name abbreviations are defined in a key

CLINICAL PATHWAY:
Perinatal HIV Exposure Management
(for Breastfeeding and Non-Breastfeeding Newborns)

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Breastmilk feeding Infants

Consult Lactation Specialist

Medications (Start in ≤ 6 hours):

- Start infant medication: AZT x4-6 wks
 - If mother desires extended therapy for infant the entire duration of breastfeeding, then consider using NVP or 3TC instead of AZT and continue until 6 wks after breastfeeding has ended

Labs:

- Birth HIV RNA, quantitative PCR, add baseline CBC and hepatic panel if NVP started
- Maternal viral load at start of breastmilk feeding if not done at delivery

Medications (start in ≤ 6 hours):

- AZT for 2-6 weeks
- OR Presumptive therapy with AZT, 3TC, and (NVP or RAL) until birth HIV PCR is negative, then AZT for 2-6 weeks

Infant Labs (HIV-1 RNA, quantitative PCR; add baseline CBC and hepatic panel if NVP or RAL started): At birth, 2-3 wks, 1-2 mo, 4-6 mo

Medications for Infant:

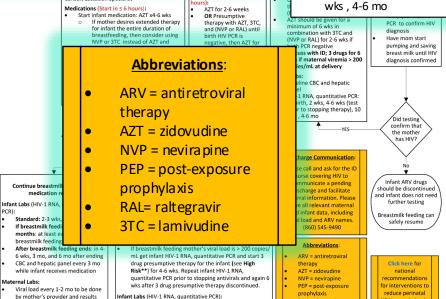
- Continue presumptive HIV therapy using AZT, 3TC, and (NVP or RAL)
- AZT should be given for a minimum of 6 wks in combination with 3TC and (NVP or RAL) for 2-6 wks if birth PCR negative
- Discuss with ID; 3 drugs for 6 wks if maternal viremia > 200 copies/mL at delivery

Infant Labs:

RAL= raltegravir

3TC = lamivudine

- Baseline CBC and hepatic panel
- HIV-1 RNA, quantitative PCR: At birth, 2 wks, 4-6 wks (test prior to stopping therapy), 10 wks, 4-6 mo



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After breastmilk feeding ends: in 4-6 wks, 3 mo, and 6



HIV transmission

the United State

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documented in infant chart

Please see
Appendix A for all ARV dosing

Appendix A provides easy access to ARV dosing

Abbreviations:

- ARV = antiretroviral therapy
- AZT = zidovudine
- NVP = nevira pine
- PEP = post-exposure prophylaxis
- RAL= raltegravir
 - 3TC = lamivudine

CLINICAL PATHWAY:

Perinatal HIV Exposure Management (for Breastfeeding and Non-Breastfeeding Newborns)
Appendix A: Antiretroviral Therapy Dosing

THIS PATHWAY SERVES AS A GUIDE AND DOES NOT REPLACE CLINICAL JUDGMENT.

Antiretroviral Therapy Dosing

Dosing for treatment based on infant gestational age at birth and post-natal age
For dosing below the recommended ages below, please consult ID

Infant AVR Dosing

Drug Name	Gestational Age, Current Age	Dose
AZT	≥35 weeks, birth to 6 weeks	4 mg/kg/dose PO BID
NVP	≥37 weeks, birth to 6 weeks	6 mg/kg/dose PO BID
3TC	≥32 weeks, birth to < 4 weeks	2 mg/kg/dose PO BID
3TC	≥ 32 weeks, ≥ 4 weeks to ≤ 6 weeks	4 mg/kg/dose PO BID
RAL	≥37 weeks, birth to 1 week AND weighing at least 2 kg	1.5 mg/kg PO once daily
RAL	≥37 weeks, 1 week AND weighing at least 2 kg	1.5 mg/kg PO BID

3 drug presumptive therapy: AZT, 3TC, and NVP or RAL

NVP Prophylaxis While Receiving Breastmilk

NVP administered starting at birth or after completion of initial prophylaxis ZDV, through 6 weeks after cessation of breastfeeding

Drug Name	Gestational Age, Current Age	Dose
NVP	≥32 weeks gestation, birth to 6 weeks AND weight 2 to <3 kg	10 mg (1 mL) PO once daily
NVP	≥32 weeks, 6 weeks to 6 months	20 mg (2 mL) PO once daily
NVP	≥32 weeks, 6 months to 9 months	30 mg (3 mL) PO once daily
NVP	≥ 32 weeks, 9 months to 18 months	40 mg (4 mL) PO once daily

(10 mg/mL oral syrup)

3TC Prophylaxis While Receiving Breastmilk

3TC administered starting after completion of initial prophylaxis ZDV, through 6 weeks after cessation of breastfeeding

Drug Name	Gestational Age, Current Age, Weight	Dose
3TC	≥32 weeks gestation, from 2 weeks to < 4 weeks	2 mg/kg/dose PO BID
3TC	≥32 weeks, ≥ 4 weeks to 12 months AND 2 to <3 kg	10 mg (1 mL) PO BID
3TC	≥32 weeks, ≥ 4 weeks to 12 months AND 3 to <4 kg	15 mg (1.5 mL) PO BID
3TC	≥32 weeks, ≥ 4 weeks to 12 months AND 4 to <8 kg	25 mg (2.5 mL) PO BID
3TC	≥32 weeks, ≥ 4 weeks to 12 months AND to ≥8 kg	50 mg (5 mL) PO BID
	(10 major), and supur)	

(10 mg/mL oral syrup)

For further dosing information including preterm infants and mothers while breastmilk feeding: https://clinicalinfo.hiv.gov/en/puldelines/pediatric-anvironagement-infants-utero-intrapartum-breastfeeding-hiv-exposure?view=ful

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Medications (start in ≤ 6 hours)

AZT for 2 weeks

Infant Labs (HIV-1 RNA, quantitative PCR):

• At 2-3 wks, 1-2 mo, 4-6 mo

- Infant labs must be followed at specific intervals for breastmilk and non-breastmilk feeding infants
- Maternal labs must be followed at specific intervals for breastmilk feeding infants to determine continued safety of breastmilk feeding

CLINICAL PATHWAY: Perinatal HIV Exposure Management (for Breastfeeding and Non-Breastfeeding Newborns)

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Breastmilk feeding Infants

Consult Lactation Specialist

Medications (Start in ≤ 6 hours):

- Start infant medication: AZT x4-6 wks
 - o If mother desires extended therapy for infant the entire duration of breastfeeding, then consider using NVP or 3TC instead of AZT and continue until 6 wks after breastfeeding has ended

Labs:

- Birth HIV RNA, quantitative PCR, add baseline CBC and hepatic panel if NVP started
- Maternal viral load at start of breastmilk feeding if not done at delivery

Medications (start in ≤ 6 hours):

- AZT for 2-6 weeks
- OR Presumptive therapy with AZT, 3TC, and (NVP or RAL) until birth HIV PCR is negative, then AZT for 2-6 weeks

Infant Labs (HIV-1 RNA, quantitative PCR; add baseline CBC and hepatic panel if NVP or RAL started): At birth, 2-3 wks, 1-2 mo, 4-6 mo

Medications (start in ≤ 6

Medications for Infant:

- Continue presumptive HIV therapy using AZT, 3TC, and (NVP or RAL)
- AZT should be given for a minimum of 6 wks in combination with 3TC and (NVP or RAL) for 2-6 wks if birth PCR negative
- Discuss with ID; 3 drugs for 6 wks if maternal viremia > 200 copies/mL at delivery

Infant Labs:

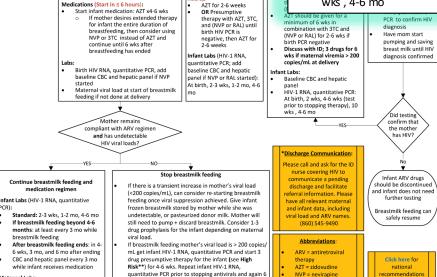
PEP = post-exposu

prophylaxis

RAL= raltegravir

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- Baseline CBC and hepatic panel
- HIV-1 RNA, quantitative PCR: At birth, 2 wks, 4-6 wks (test prior to stopping therapy), 10 wks, 4-6 mo



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fant Labs (HIV-1 RNA, quantitative PCR):

wks after 3 drug presumptive therapy discontinued.

After breastmilk feeding ends: in 4-6 wks, 3 mo, and 6



for interventions:

reduce perinatal

the United States

HIV transmission

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Viral load every 1-2 mo to be done

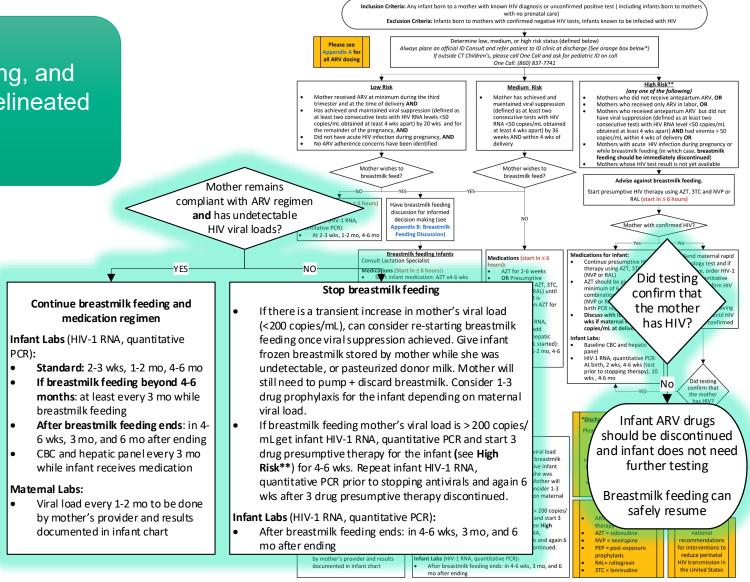
by mother's provider and results

documented in infant chart

Continued ARV prophylaxis, lab monitoring, and breastmilk feeding indications are also delineated in this clinical pathway

CLINICAL PATHWAY: Perinatal HIV Exposure Management (for Breastfeeding and Non-Breastfeeding Newborns)

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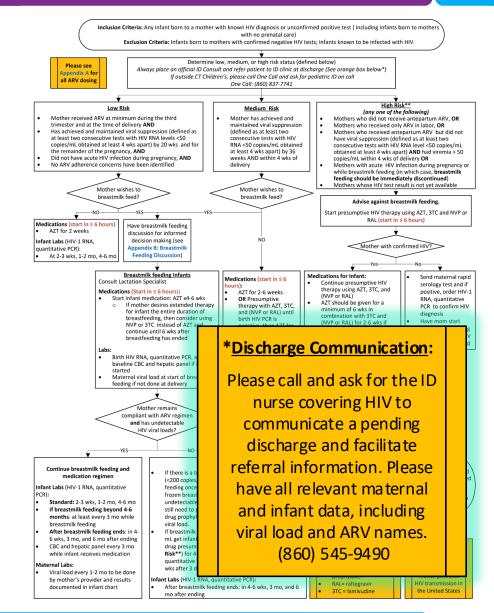
 $\textbf{CONTACTS:} \ A \textbf{SHLEY HOWARD,} \ DO \ | \ IAN \ MICHELOW, \ MD \ | \ A \textbf{LAINA PYLE,} \ MD \ | \ NANNETTE \ KYER, \ BSN, \ RN, \ IBCLC$



- As mentioned earlier, communication with Pediatric Infectious Diseases is paramount throughout the hospitalization, but also at the time of hospital discharge.
- Please contact the ID nurse covering the HIV clinic for any pending discharge to plan following care.

CLINICAL PATHWAY:
Perinatal HIV Exposure Management
(for Breastfeeding and Non-Breastfeeding Newborns)

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Review of Key Points



- Infants do not all receive the same perinatal HIV medications and are stratified by risk based on maternal factors
 - Antiviral medication for infants should be started within 6 hours of birth
- Exclusive breastmilk feeding for infants born to women living with HIV is now supported if the parent is medication compliant and virally suppressed
 - Infants still need antiviral medication after birth
 - Mixed feeding is discouraged
- Pediatric ID always wants to be involved in decision making and long-term care for HIV perinatally exposed infants

Quality Metrics (Under Development)



- Number of infants who are eligible for the pathway
- Number of eligible infants who are determined to be at low, medium or high risk of acquiring HIV
- Number of eligible infants who get HIV testing at birth
- Number of mothers living with HIV who choose to breastmilk feed (exclusive vs mixed feeding)
- Number of prenatal consults performed by nursery providers and ID to provide counseling for breastmilk feeding

Pathway Contacts



- Ashley Howard, DO, Pediatric Infectious Diseases
- Ian Michelow, MD, Pediatric Infectious Diseases
- Alaina Pyle, MD, Neonatology
- Nannette Kyer, BSN, RN, IBCLC

References



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Thank You!



About Connecticut Children's Pathways Program

Clinical pathways guide the management of patients to optimize consistent use of evidence-based practice. Clinical pathways have been shown to improve guideline adherence and quality outcomes, while decreasing length of stay and cost. Here at Connecticut Children's, our Clinical Pathways Program aims to deliver evidence-based, high value care to the greatest number of children in a diversity of patient settings. These pathways serve as a guide for providers and do not replace clinical judgment.