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

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

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

Please see Appendix A for all ARV dosing

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 acute 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 delivery

High Risk**
(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

Mother wishes to breastmilk feed?

Mother wishes to breastmilk feed?

Advise against breastmilk feeding.
Start presumptive HIV therapy using AZT, 3TC and NVP or RAL **(start in ≤ 6 hours)**

Mother with confirmed HIV?

NO — YES — YES — NO — Yes — No

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

Have breastmilk feeding discussion for informed decision making (see **Appendix B: Breastmilk Feeding Discussion**)

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:
- 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

- Send maternal rapid serology test and if positive, order HIV-1 RNA, quantitative PCR to confirm HIV diagnosis
- Have mom start pumping and saving breast milk until HIV diagnosis confirmed

Did testing confirm that the mother has HIV?

YES — No

Mother remains compliant with ARV regimen **and** has undetectable HIV viral loads?

YES — NO

Continue breastmilk feeding and medication regimen

Infant Labs (HIV-1 RNA, quantitative PCR)**:**
- **Standard:** 2-3 wks, 1-2 mo, 4-6 mo
- **If breastmilk feeding beyond 4-6 months**: at least every 3 mo while breastmilk feeding
- **After breastmilk feeding ends**: in 4-6 wks, 3 mo, and 6 mo after ending
- CBC and hepatic panel every 3 mo while infant receives medication

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

Stop breastmilk feeding
- If there is a transient increase in mother's viral load (<200 copies/mL), can consider re-starting breastmilk feeding once viral suppression achieved. Give infant frozen breastmilk stored by mother while she was undetectable, or pasteurized donor milk. Mother will still need to pump + discard breastmilk. Consider 1-3 drug prophylaxis for the infant depending on maternal viral load.
- If breastmilk feeding mother's viral load is > 200 copies/mL get infant 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 prior to stopping antivirals and again 6 wks after 3 drug presumptive therapy discontinued.

Infant Labs (HIV-1 RNA, quantitative PCR)**:**
- After breastmilk feeding ends: in 4-6 wks, 3 mo, and 6 mo after ending

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

Abbreviations:
- ARV = antiretroviral therapy
- AZT = zidovudine
- NVP = nevirapine
- PEP = post-exposure prophylaxis
- RAL= raltegravir
- 3TC = lamivudine

No

Infant ARV drugs should be discontinued and infant does not need further testing

Breastmilk feeding can safely resume

Click here for national recommendations for interventions to reduce perinatal HIV transmission in the United States

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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 mg/mL oral syrup)

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

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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
- Celiac Disease
- Crohn's Disease and ulcerative colitis
- Late-onset sepsis in preterm infants
- Type 1 and type 2 diabetes
- Leukemia
- Childhood overweight and obesity

Maternal Benefits:

- Decreased risk of breast, ovarian, endometrial, and thyroid cancers
- Decreased risk of hypertension
- Decreased risk of type 2 diabetes
- Decreased risk of rheumatoid arthritis

Maternal ART compliance is important in breastmilk feeding to help keep baby safe. The infant can be infected through breastmilk feeding because the HIV virus can be in the breastmilk if someone does not take their HIV medication. The baby can receive medication up to 4-6 weeks or longer to help keep this from happening. Maternal viral load testing every 1-2 months is important. If there is detectable maternal virus, then the mother needs to stop breastfeeding and call for further instructions. Infants will also continue to be tested according to a set schedule during this time as well, but at least every 3 months.

When someone is breastmilk feeding it is recommended mix feed with formula as little as possible, as older studies showed a higher rate of infant HIV infection with "mixed" feeding.
When should formula be considered?

- The infant is losing weight
- The breastmilk supply is not yet established
- There is not enough stored breast milk

When should solid foods be introduced? Solid foods should be introduced at 6 months of age when breastmilk feeding with HIV.

It is important to stop breastfeeding if: A mother has mastitis (swollen, red, and tender breasts) or open sores/bleeding from the breast. It is important to pump during this time and discard the breastmilk. Stored frozen breastmilk can be safely given at this time.

References can be accessed at:
www.aap.org/en/patient-care/breastfeeding/breastfeeding-overview/
https://clinicalinfo.hiv.gov/en/guidelines/perinatal/infant-feeding-individuals-hiv-united-states

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