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

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MAGNET RECOGNIZED

BEST CHILDREN'S HOSPITAL

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 life[1]
  - > 1 month of age 0.6% - 0.9% per month[2]
    - Mixed feeding associated with higher
    - Exclusive BF associated with lower rates

American Academy of Pediatrics Benefits of Breastfeeding[3]:

Child Benefits:

- Improved dental health
- Improved neurodevelopmental outcomes
- Decreased risk of:
  - Otitis media
  - Respiratory tract infection
  - Necrotizing enterocolitis
  - 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

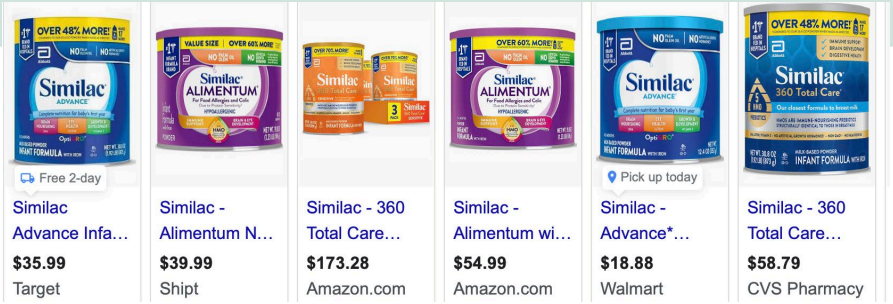
Other Influences:

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 Study[4]

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).**

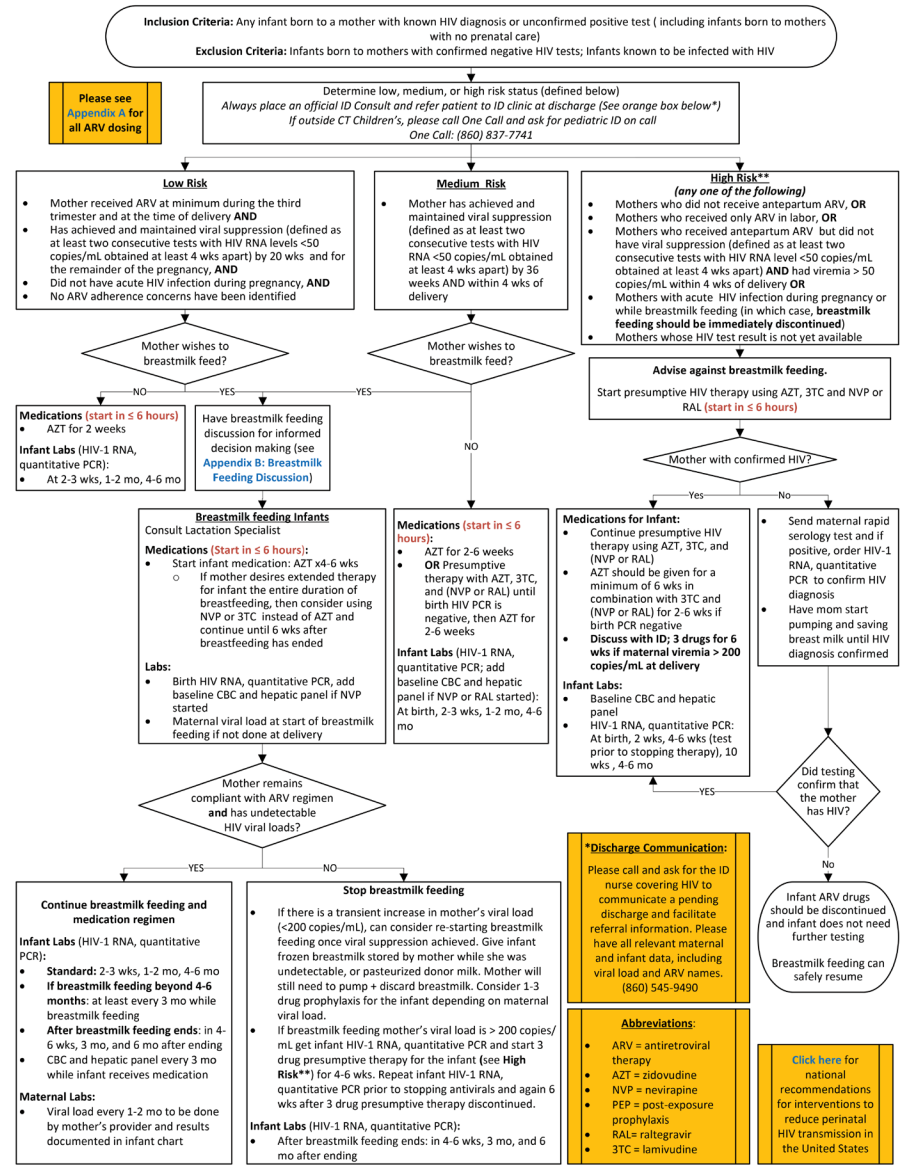
https://clinicalinfo.hiv.gov

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 GUIDE AND DOES NOT REPLACE CLINICAL JUDGMENT.



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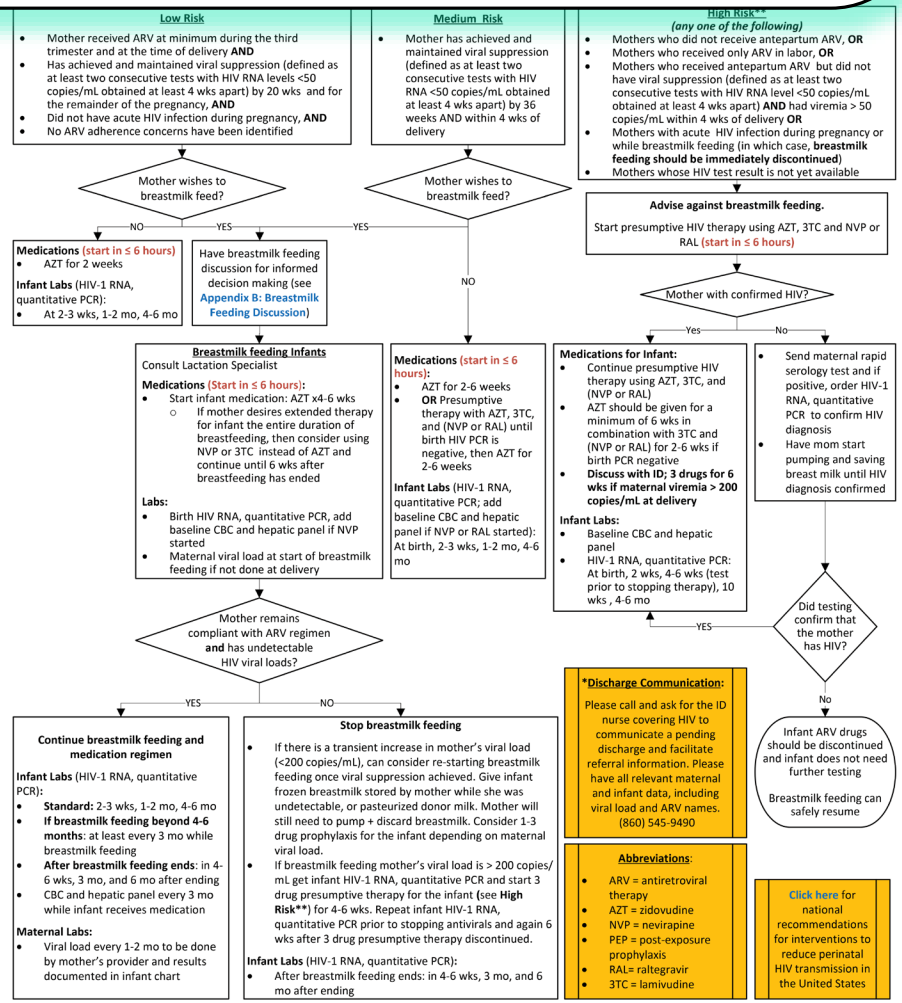
Inclusion Criteria: Any infant born to a mother with known HIV diagnosis or unconfirmed positive test (including infants born to mothers with no prenatal care)

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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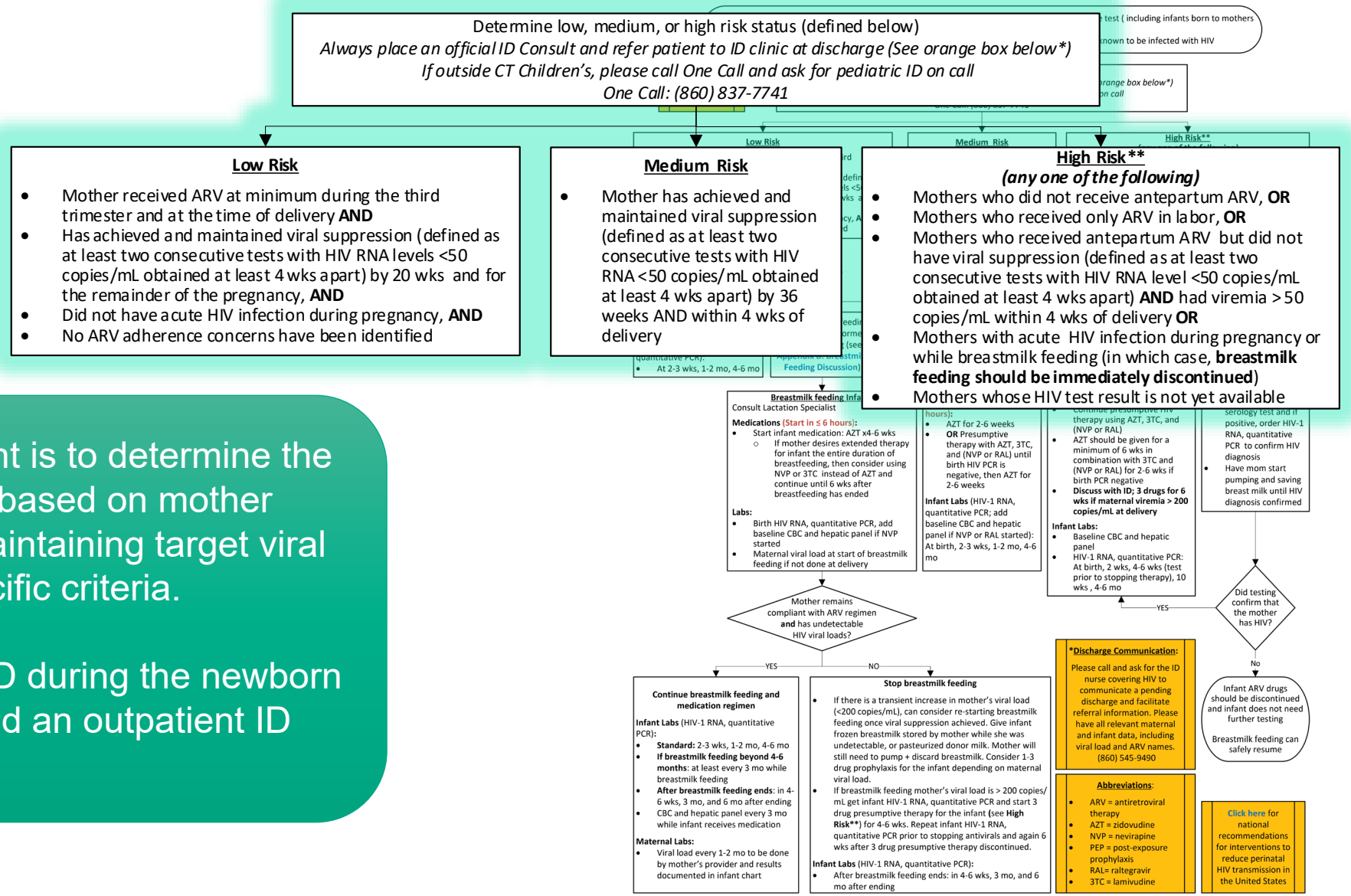
- The first step in management is to determine the infant's risk status, which is based on mother receiving ARV, achieving/maintaining target viral suppression, and other specific criteria.
- ALWAYS consult Pediatric ID during the newborn hospital admission AND send an outpatient ID referral



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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:
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Appendix B: Informed Discussion for Caregivers Living with HIV and Breastmilk Feeding

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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

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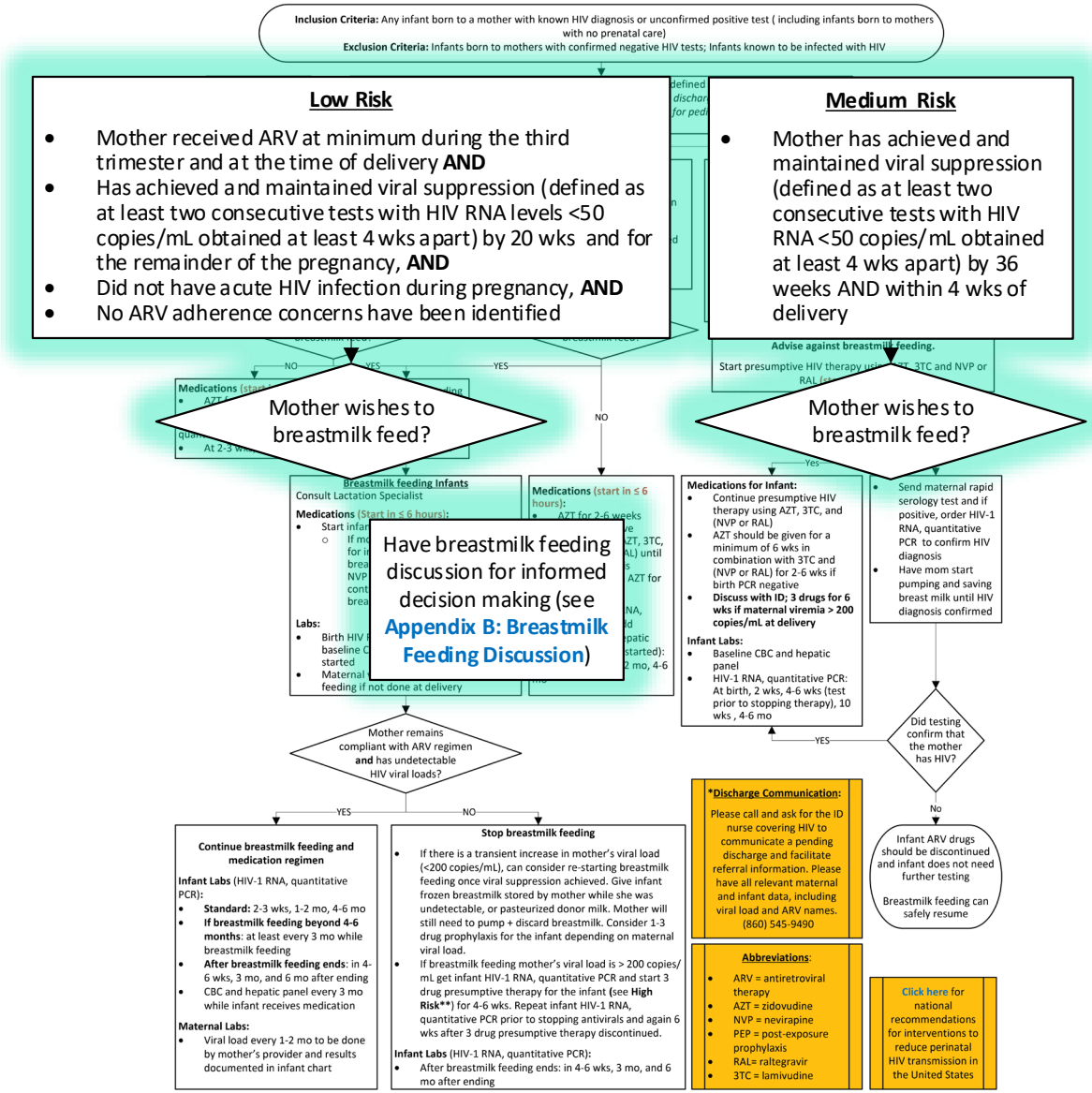

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- It is inadvisable for “high-risk” infants to breastmilk feed

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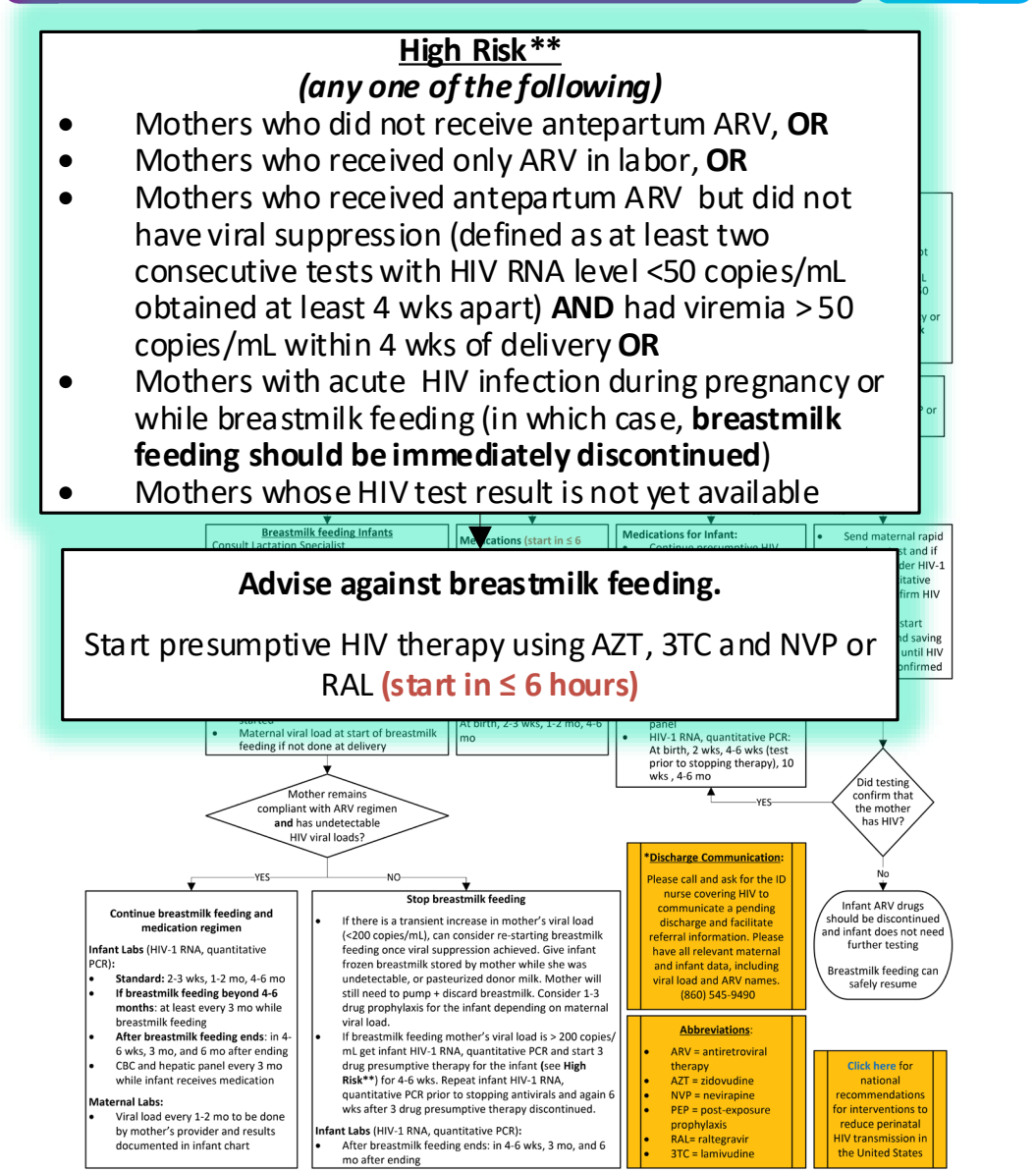

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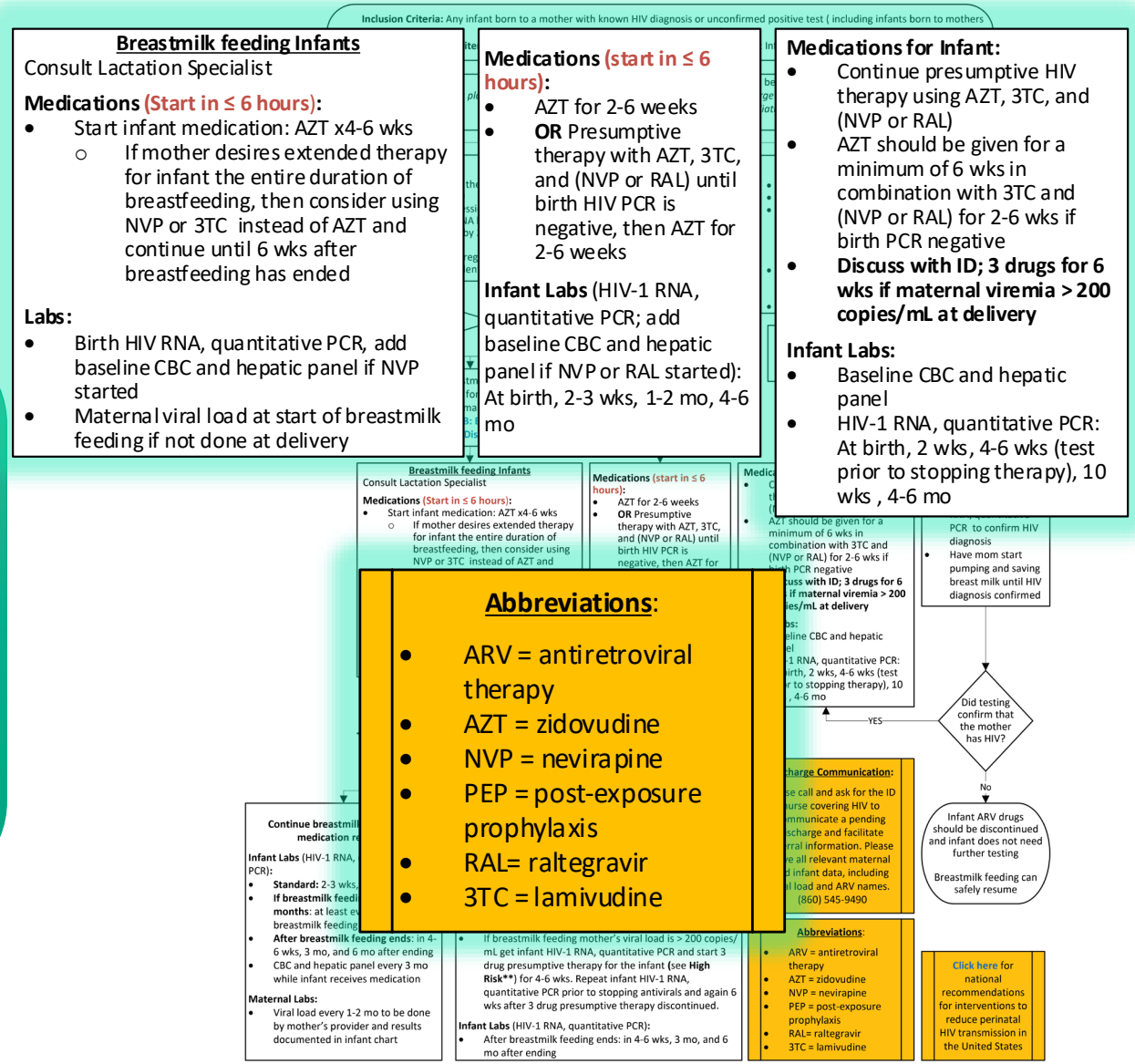
Medications (start in ≤ 6 hours)
- AZT for 2 weeks

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



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Please see Appendix A for all ARV dosing

Appendix A provides easy access to ARV dosing

Abbreviations:

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

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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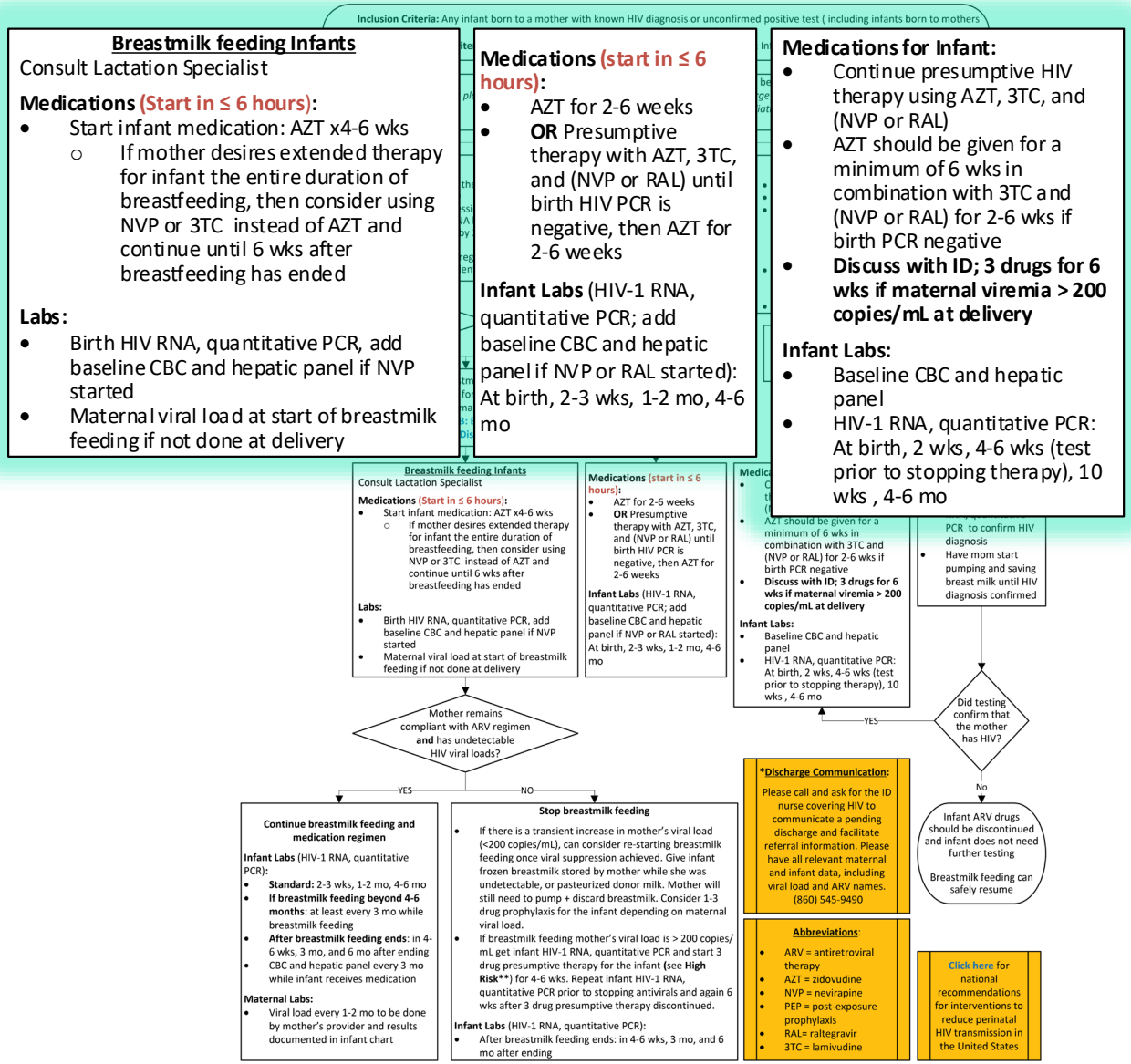
Infant Labs (HIV-1 RNA, quantitative PCR):
- At 2-3 wks, 1-2 mo, 4-6 mo

- **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



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

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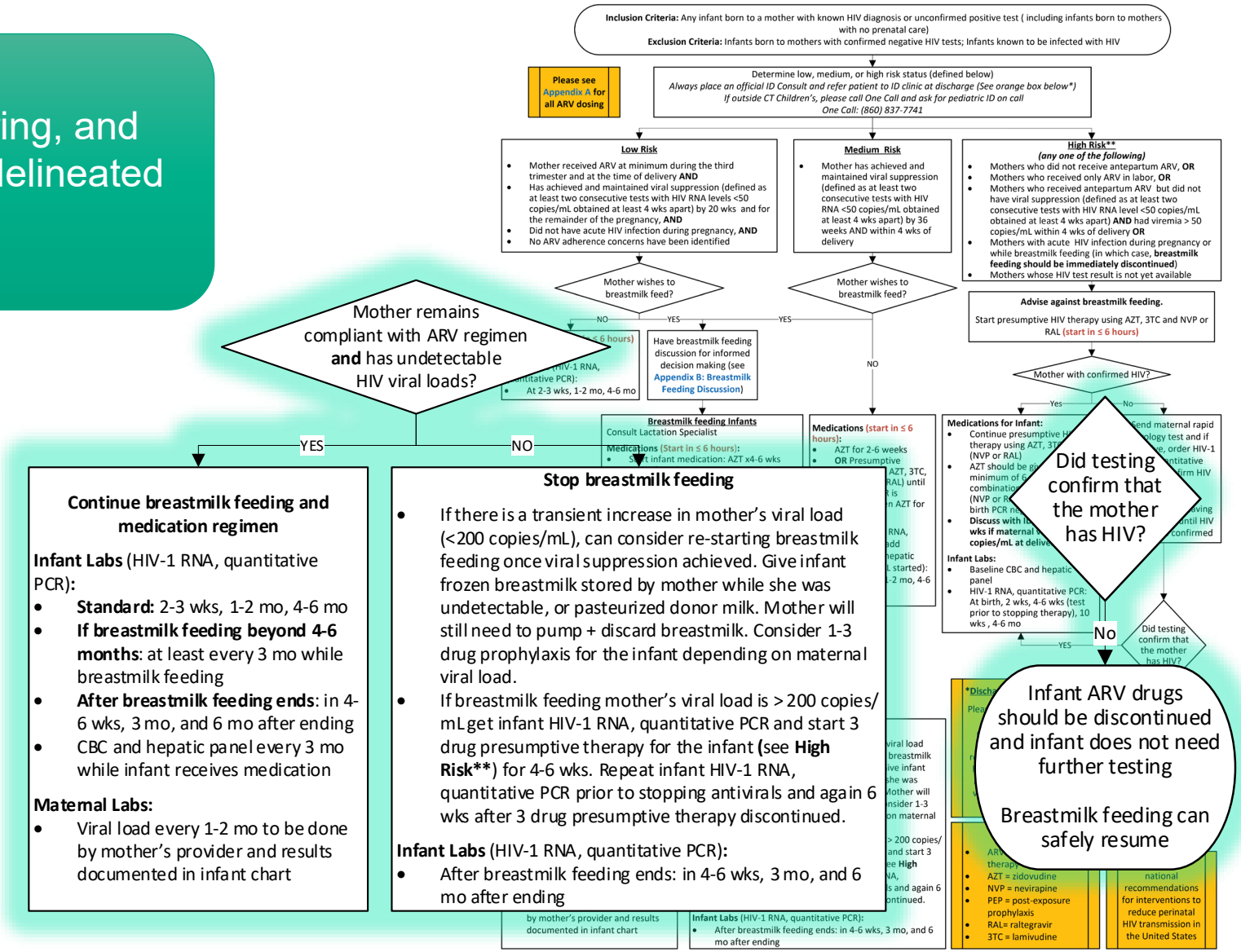

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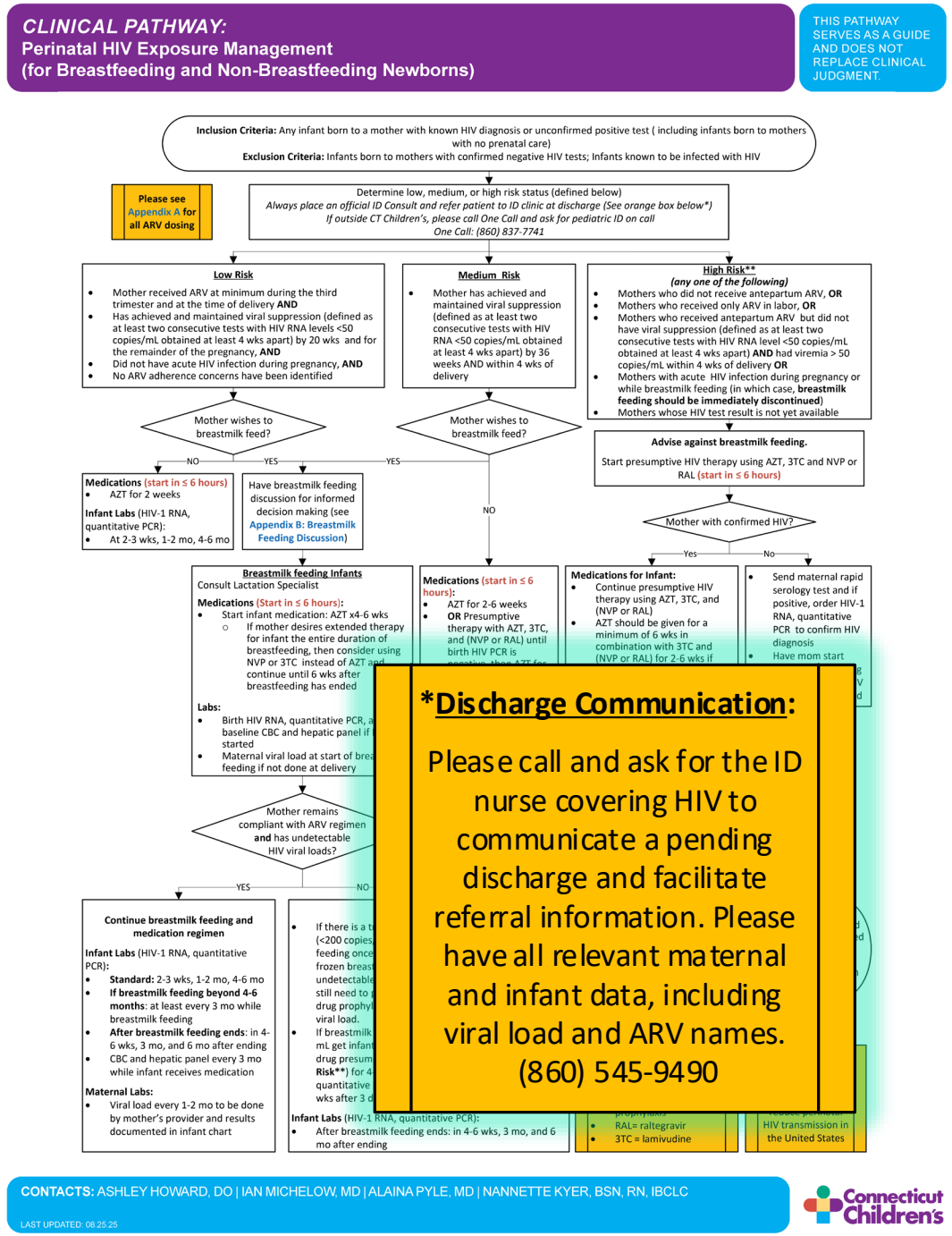
- As mentioned earlier, communication with Pediatric Infectious Diseases is paramount throughout the hospitalization, but also at the time of hospital discharge.
- Please contact the ID nurse covering the HIV clinic for any pending discharge to plan following care.



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.