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NHS Foundation Trust

Trust Guideline for the Management of Infants Born to HIV Positive Mothers

A clinical guideline recommended

For use in:	Neonatal Intensive Care Unit and Blakeney (postnatal) Ward
By:	Neonatal Medical and Nursing staff
For:	Infants born to HIV positive mothers
Division responsible for document:	Women and Children's Services Division
Key words:	HIV, Infant, Vertical transmission
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To be reviewed by:	Dr Florence Walston
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Compliance links: *(is there any NICE related to guidance)*	Yes – BHIVA - https://www.bhiva.org/pregnancy-guidelines
If Yes – does the strategy/ policy deviate from the recommendations of NICE? If so, why?	No

This guideline has been approved by the Trust's Clinical Guidelines Assessment Panel as an aid to the diagnosis and management of relevant patients and clinical circumstances. Not every patient or situation fits neatly into a standard guideline scenario and the guideline must be interpreted and applied in practice in the light of prevailing clinical circumstances, the diagnostic and treatment options available and the professional judgement, knowledge and expertise of relevant clinicians. It is advised that the rationale for any departure from relevant guidance should be documented in the patient's case notes.

The Trust's guidelines are made publicly available as part of the collective endeavour to continuously improve the quality of healthcare through sharing medical experience and knowledge. The Trust accepts no responsibility for any misunderstanding or misapplication of this document.

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Version and Document Control:

Version Number	Date of Update	Change Description	Author
7	04/11/2021	Major rewrite	Dr Florence Walston

This is a Controlled Document

Printed copies of this document may not be up to date. Please check the hospital intranet for the latest version and destroy all previous versions.

Trust Guideline for the Management of Infants Born to HIV Positive Mothers

1. Introduction

1.1. Up to Date Practice

This document must be read in conjunction with the most up to date guidelines - Guidelines for the Management of HIV in Pregnancy and Postpartum 2018 (2020 third interim update) - **https://www.bhiva.org/pregnancy-guidelines**.

1.2. Objective

To reduce vertical transmission of Human Immunodeficiency Virus (HIV).

1.3. Rationale

Without intervention there is a high risk of transmission of HIV from mother to infant (estimates vary from 25%-40%). However, vertical transmission of HIV has almost been eliminated, thanks to the antenatal HIV screening programme for pregnant women in the UK with treatment offered to both mother and baby (PHE). Active management before, during and after labour and into the neonatal period can reduce the risk of transmission to well under 1%.

1.4. Broad recommendations

All pregnant women who have tested positive for HIV infection should be offered a multidisciplinary management for them and their baby.

A Perinatal Birth Plan is written by the Neonatal Consultant (after consultation with parents, iCASH, Midwifery and Obstetric departments) in anticipation of the delivery of the infant. The will include:

- Maternal anti-retroviral therapy antepartum and intrapartum.
- Most up to date maternal viral load.
- Planned mode of delivery.
- Post Exposure Prophylaxis plan for the baby.
- Planning regarding of breastfeeding.

1.5. HIV-1 infection

This guideline refers to women with HIV-1 infection. For women infected with HIV-2, see *Section 3.2.3.*

2. Clinical Management - Maternal

2.1. Antepartum Management

There is a separate Trust guideline (**NNUH Protocol for the Management of HIV in Pregnancy)** that deals in detail with maternal management and this should be referred to for more information.

All pregnant women are offered HIV testing as part of routine antenatal screening. Any pregnant woman found to be HIV positive will be referred to genito-urinary medicine (iCASH).

An initial antenatal review appointment is arranged with a neonatologist when the HIV positive status of the mother is reported by the Genitourinary or Obstetric departments. At this meeting, there is a discussion with the mother regarding the nature of risk to her infant and how this risk can be minimized. A **Perinatal Birth Plan** is then written by the NICU consultant, based upon most up to date information. This is copied to the mother, the iCASH consultant, Obstetric consultants and to the general practitioner, as well as being copied to the Neonatal Alert Folder.

2.2. Maternal Viral Load

Maternal viral loads will be communicated to the obstetric and neonatal team by iCASH. Birthplans will be updated with these results. Women who commence cART in pregnancy need an HIV viral load; 2-4 weeks after commencing cART, at least once every trimester, at 36 weeks, and at delivery.

As critical decisions relating to categorisation of risk for the infant relate directly to the maternal viral load at the time of delivery, BHIVA recommends that this result should be available as early as possible and certainly within 72 hours of delivery. In the event of the results not being available, please contact the on call virologist through switchboard.

2.3. Maternal Drug Treatment

All mothers will be on antiretroviral treatment with monitoring of their viral loads carried out by iCASH with an aim to reduce the viral load to <50 RNA copies/ml at the time of delivery. Therapy is guided by CD4 count, viral load and genotypic resistance testing. Resistance may alter Post Exposure Prophylaxis for the infant. *See Section 3.2.1.*

2.4. Delayed Cord Clamping

Although currently the WHO (2012) recommends that the proven benefits delayed cord clamping (DCC) outweigh the theoretical harms of DCC, in the UK and Europe many centres advise against it in HIV positive mothers. Until further advice from BHIVA is available, we too recommend against DCC.

2.5. Preterm Delivery

Threatened premature labour should be treated in the same way as HIV negative women with regard to steroids and magnesium which should be used where indicated.

3. Clinical Management - Neonatal

3.1. Perinatal Birth Plan

To ensure the most appropriate, patient-centered treatment, it is vital to treat the infant according to the plan documented in the most up to date Perinatal Birth Plan. This will be filed in the Neonatal Alert Folder and available on the Electronic Template under the mother's details. It is still important to confirm at delivery that the infant is in the same risk group (*see Section 3.2.1*). NICU consultant writing birth plan will liaise with pharmacy regarding infants in the high risk category to ensure stock of

medicines required to start within 4 hours of delivery. Not all medicines are routinely stocked in baby friendly formulations therefore it is necessary to do this in advance.

If there is any doubt about the plan or risk group, please discuss urgently with the on call NICU/Obstetric/Virology Consultant to ensure the most appropriate therapy is started in a timely fashion.

3.2. Postnatal Management

The 4 main components of initial care are:

- Post Exposure Prophylaxis (PEP) – this will be dependent on the infant's risk group: VERY LOW RISK, LOW RISK or HIGH RISK (*see Section 3.2.1*).
- The infant should be washed with soap and water to remove blood.
- Blood tests for HIV status (*see Section 3.4).*
- Avoidance of breastfeeding unless planned in MDT discussions antenatally – see Perinatal Birth Plan and Infant Feeding (*see Section 3.1 and 3.3*).

3.2.1. Post Exposure Prophylaxis (PEP)

Neonatal PEP should be commenced as soon as possible after birth, and at least within 4 hours.

PEP will depend upon the risk of the infant (see below and *Figure 1*). This will be documented in the Perinatal Birth Plan (*see Section 3.1*).

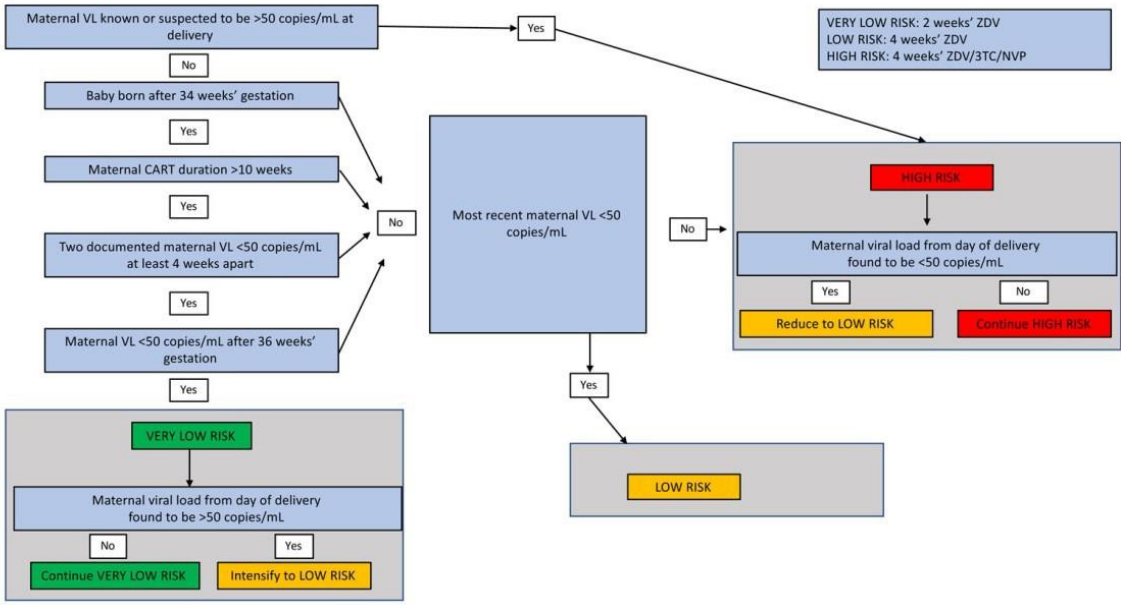
- It is vital to check the mother's most recent viral load to ensure the correct risk allocation for the infant.
- Oral and IV zidovudine are kept on Delivery Suite.

VERY LOW RISK	
Criteria	• The woman has been on cART for longer than 10 weeks. **AND** • Two documented maternal HIV viral loads <50 HIV RNA copies/mL during pregnancy at least 4 weeks apart prior to 36 weeks. **AND** • Maternal HIV viral load <50 HIV RNA copies/mL at or after 36 weeks.
Post Exposure Prophylaxis *See Appendix 1 for dosing*	**Two weeks of zidovudine monotherapy** In the context of known maternal resistance to zidovudine with **VERY LOW RISK**, zidovudine monotherapy is still recommended for infant PEP.

LOW RISK	
Criteria	• If the criteria in VERY **LOW RISK** are not all fulfilled but maternal HIV viral load is <50 HIV RNA copies/mL at or after 36 weeks; or

	• If the infant is born prematurely (<34 weeks) but most recent maternal HIV viral load is <50 HIV RNA copies/mL. (*see Section 3.2.2*)
Post Exposure Prophylaxis *See Appendix 1 for dosing*	**4 weeks of zidovudine monotherapy** In the context of known maternal resistance to zidovudine with **LOW RISK**, zidovudine monotherapy is still recommended for infant PEP.
HIGH RISK	
Criteria	• If maternal birth HIV viral load is known to be or likely to be >50 HIV RNA copies/mL on day of birth. **OR** • If uncertainty about recent maternal adherence. **OR** • If viral load is not known.
Post Exposure Prophylaxis *See Appendix 1 for dosing*	**Combination PEP – in discussion with virology** The recommended regimen for standard three-drug PEP is • 2 weeks of nevirapine (at full or incremental dosing). • 4 weeks of zidovudine and lamivudine. If **HIGH RISK** and there is a history of documented maternal zidovudine and/or nevirapine resistance, seek expert advice. If advice is not immediately available, commence standard three-drug PEP (zidovudine, lamivudine and nevirapine) until guidance is provided.

Figure 1 - Algorithm for infant treatment



3.2.2. Intravenous ART in the neonate in Sick/Premature Infants

The only licensed ART available for intravenous use in sick and/or premature neonates who are unable to take oral medication is zidovudine. Reduced oral and intravenous dosing schedules for premature infants are available (*see Appendix 1*).

It is not known whether very early enteral administration of ART can exacerbate the risk of necrotising enterocolitis. Premature infants should be commenced on intravenous zidovudine until enteral feeding is established, when zidovudine may be given enterally. The premature dosing regimen should be used (*see Appendix 1*).

3.2.3. HIV-2

If a woman is known to have HIV-2 infection, follow the above advice as for HIV infant PEP but if HIGH RISK (combination PEP indicated) nevirapine will not be effective. Seek expert advice (on call virology). If advice is not immediately available, commence zidovudine, lamivudine and raltegravir until guidance is available (*see Appendix 1*).

3.2.4. Infant PEP beyond 4 weeks

Infant PEP should not be given beyond 2 weeks for VERY LOW-RISK or 4 weeks for LOW-RISK infants even if the infant is breastfed.

PEP should not be restarted unless significant subsequent exposure (e.g. maternal viral load detectable during breastfeeding). Seek expert advice regarding need for PEP following breast milk exposure during an episode of maternal viraemia.

3.3. Infant feeding

In the UK and other high-income settings, the safest way to feed infants born to women with HIV is with formula milk, as there is on-going risk of HIV exposure after birth. BHIVA continues to recommend that women living with HIV feed their babies with formula milk.

Some women are keen to breast feed and, in specific circumstances, this should be supported with appropriate counselling. (*see Section 1.4*). There are no data on the risk of HIV transmission via breast milk in high-income countries. In a low-middle income trial with women on cART throughout the breastfeeding period the transmission rate was 0.3% (95% CI 0.1–0.6) at 6 months and 0.6% (95% CI 0.4 – 1.1) at 12 months (*Taha T et al*).

Factors that increase the risk of HIV transmission via breast milk when women are not on cART include:

- Detectable HIV viral load;
- Advanced maternal HIV disease;
- Longer duration of breastfeeding;
- Breast and nipple infection/inflammation;
- Infant mouth or gut infection/inflammation;
- Mixed feeding, in particular solid food given to infants less than 2 months of age (*Becquet R et al*).

Where a woman is on cART and breastfeeding, it is presumed that the same factors are relevant, albeit less so, depending on adherence and viral load suppression. See section 3.3.2 for further information.

3.3.1. Supporting women living with HIV to formula feed

It is important to be aware that not breastfeeding can come at an emotional, financial and social cost to women living with HIV (*Tariq S, et al; National AIDS Trust*) and we advise that women receive appropriate support from their HIV MDT (which may include peer support, psychological and practical support, and financial support for formula feeding).

Women not breastfeeding their infant by choice, or because of viral load >50 HIV RNA copies/mL, should be offered cabergoline to suppress lactation. This will be arranged by the obstetric and midwifery team.

3.3.2. Choosing to breastfeed in the UK

Feeding plans will be made antenatally and will be documented in the Neonatal Birth Plan. Any new plans to breast feed should be discussed with the consultant on call and the virologist on call.

Women who are virologically suppressed on cART with good adherence and who choose to breastfeed should be supported to do so if they are fully counselled by a consultant multidisciplinary team as to the risks, and fulfil the following criteria:

- A fully suppressed HIV viral load (for as long a period as possible, but certainly during the last trimester of pregnancy);
- A good adherence history;
- Strong engagement with the perinatal MDT;
- Prepared to attend for monthly clinic review and blood HIV viral load tests for themselves and their infant during and for 2 months after stopping breastfeeding (*see Section 3.4*).

They should be advised of the small on-going risk of HIV transmission through breastfeeding and the requirement for extra maternal and infant clinical monitoring. They should be aware that the risk of transmission in women on cART increases according to the duration of breastfeeding (*Nagot N et al*). The decision will be finalised as part of pre-birth MDT discussions and documented in the Perinatal Birth Plan.

Where a plan is made to breast feed, women should be provided **with Patient Breast Feeding Information Leaflet One and Two** from BHIVA (www.bhiva.org/pregnancy-guidelines) and advised:

- To breastfeed for as short a time as possible.
- To exclusively breastfeed for the first 6 months.
- To cease breastfeeding if they have breast infection/mastitis or if they or their infant has gastrointestinal symptoms.
- Given clear information, including how to manage common complications of breastfeeding, and have ready access to clinical advice and peer support.
- When weaning to solids, women should follow standard UK guidance, introducing complementary foods after 6 months of age, if still breastfeeding.

Abrupt weaning from breast to formula and/or solids can be avoided, as long as the maternal HIV viral load remains fully suppressed.

Women who **do not** fulfil the above criteria should be advised against breastfeeding:

- Women whose infants fall into the LOW-RISK category because of a short duration of cART and viral suppression or because of prematurity should be counselled that their risk of transmission may be higher because of a higher risk of transient viral expression in plasma and breast milk, and because of the immature neonatal gut.
- Women who breastfeed with a known detectable HIV viral load should be referred to social care as this places their infant at significant risk of HIV infection. A supportive and harm reduction approach of working openly together should be taken, to maintain trust and reduce the risk of women being pressurised to breastfeed in secret (*Tariq S et al; Johnson G et al*).

Maternal cART (rather than infant pre-exposure prophylaxis [PrEP]) is advised to minimise HIV transmission through breastfeeding and safeguard the woman's health. There is no need to extend infant PEP beyond 2 weeks simply because of breastfeeding if all of the criteria for VERY LOW RISK are met.

When a woman decides to breastfeed, she and her infant should be reviewed monthly in clinic for HIV RNA viral load testing during and for 2 months after stopping breastfeeding.

3.4. Diagnosis of HIV status

Non-breastfed infants	
Molecular diagnostics for HIV infection	**Sample to Order on ICE**
• **Birth** (During the first 48 hours and prior to hospital discharge). • **6 weeks** (or at least 2 weeks after cessation of infant prophylaxis). • **12 weeks** (or at least 8 weeks after cessation of infant prophylaxis). • On other occasions if additional risk including at **2 weeks** of age if **HIGH RISK** at delivery.	**Neonatal HIV proviral DNA (EDTA)** ***NOT*** *cord blood.* *Book as* ***OUTPATIENT*** *on ICE to ensure reviewed by consultant.* The **birth** sample must have a paired maternal sample: **Paired Maternal HIV Proviral DNA (EDTA).**
Antibody testing	
• If the mother's antibody status is not documented, an HIV antibody test should be performed on the first sample from the infant. • **22–24 months** - HIV antibody testing for seroreversion should be. • Although an HIV antibody test may be negative before this time, engagement in care should continue until at least 18 months of age.	**HIV serology (this provides anti-HIV antibody) –** (clotted).

Breastfed infants	
Molecular diagnostics for HIV infection	**Sample to Order on ICE**
• **Birth** (During the first 48 hours and prior to hospital discharge). • **2 weeks of age.** • **Monthly** for the duration of breastfeeding; • At **4 and 8** weeks after cessation of breastfeeding.	**Neonatal HIV proviral DNA (EDTA)** ***NOT*** *cord blood* *Book as* ***OUTPATIENT*** *on ICE to ensure reviewed by consultant.* The **birth** sample must have a paired maternal sample: **Paired Maternal HIV Proviral DNA (EDTA).**
Antibody testing	
• If the mother's antibody status is not documented, an HIV antibody test should be performed on the first sample from the infant. • HIV antibody testing for seroreversion should be checked at age **22–24 months**, or at a minimum of 8 weeks after cessation of breastfeeding, if this is later.	**HIV serology (this provides anti-HIV antibody) –** (clotted)

3.5. Neonatal management in maternal hepatitis co-infection

Follow local guidance for management of maternal HBV/HCV in pregnancy and discuss with virology consultant.

3.6. Immunisation

Immunisations should be given as per the national schedule outlined in the Green Book.

- Rotavirus vaccine is not contraindicated (unless HIV diagnosis has been confirmed and infant is severely immunosuppressed).
- If there is VERY LOW or LOW RISK of HIV transmission and BCG at birth is indicated as per UK guidelines, this should not be delayed.

3.7. Pneumocystis pneumonia (PCP) prophylaxis

Co-trimoxazole prophylaxis is recommended from 1 month of age if HIV PCR screening is positive at any stage or if the infant is confirmed to be diagnosed with HIV. This should only be stopped if HIV infection is subsequently excluded.

3.8. HIV Exposed but Uninfected (HEU)

There is a growing body of evidence, mainly from observational studies in low- and middle-income countries, for possible increased infectious morbidity in HIV exposed but uninfected (HEU) children in early life (*Evans C et al; Afran L et al*). Multiple potential confounding factors make interpretation and conclusions from such studies challenging. *In utero* exposure to an altered maternal immune system and ART have

both been proposed as potential factors contributing to an impairment in HEU neonatal immunity (*Afran L et al*). Much less information is available from high-income settings and findings are inconsistent (*Taron-Brocard C et al; Epalza C et al; Adler e Ct al; Macdonald EM, et al*).

In view of these concerns, although it remains to be demonstrated that HEU children in the UK are at increased risk of morbidity, BHIVA recommends:

- All healthcare professionals involved in the care of HEU children in early life are made aware of this potential additional risk factor.
- The need for timely and complete routine immunisations should also be emphasised.

3.9. Follow-Up

Please inform Dr Walston on discharge of any infant at risk of vertical transmission of HIV via email, cc NeonatalSecretaries@nnuh.nhs.uk

- For non-breast fed **VERY LOW RISK** and **LOW RISK**, please book the infant into Florence Walston's Clinic at 6 weeks of age.
- For **HIGH RISK** infants, a blood test will be needed at 2 weeks. This should be arranged pre discharge. Please also book the infant into Florence Walston's Clinic at 6 weeks of age
- **Breast feeding infants and HIGH RISK infants** will need to be discussed with Florence Walston / on call consultant and virology pre discharge to allow tailored follow up to be arranged.

4. Management of infants diagnosed with HIV

In the event of an infant being diagnosed with HIV, an immediate, **URGENT** repeat test on a new sample should be requested to confirm infection.

Infants with a positive test for HIV should be referred urgently to the local NNUH paediatrics specialist to initiate infant cART. They will liaise with a specialist centre for management of HIV according to Children's HIV Association (CHIVA) and Paediatric European Network for Treatment of AIDS (Penta) guidelines.

When an infant is diagnosed with HIV, PCP prophylaxis should be started as soon as the baby reaches age 4 weeks, or immediately if the infant is already aged more than 4 weeks (*see Section 3.7*).

A positive HIV diagnosis in an infant should be fed back to the obstetric unit where the infant was born to allow investigation of any avoidable factors in transmission.

5. Communication with Health Professionals

With sensitivity to concerns about confidentiality, women should be strongly encouraged to inform partners/families and healthcare providers (including midwives, health visitors and GPs) and anyone else involved in their care (such as lactation consultants) about their HIV status. This will enable the family and local team to give appropriate support and advice, especially regarding feeding, vaccinations and

medical assessment of the infant. This will be done throughout pregnancy by the MDT Team (iCASH, Obstetrics, midwifery and Neonatal Consultant).

6. Clinical Audit Standards

Offering an antenatal review appointment with a neonatologist when the HIV positive status of the mother is reported to the Genitourinary or Obstetric departments.

Administration of zidovudine/appropriate ART within 4 hours of birth.

Adherence to the suggested schedule for blood tests with regard to sampling and timing.

7. Summary of development and consultation process undertaken before registration and dissemination

The guideline was drafted by the authors listed above, as an update of a previous guideline, after consultation with obstetric, virology and genito-urinary medicine departments. It has been presented and discussed at the neonatal department guidelines meeting and amended accordingly.

This version has been endorsed by the Clinical Guidelines Assessment Panel.

8. Distribution list/ dissemination method

Neonatal intensive care
Delivery suite
Blakeney ward
Cley ward
Trust Intranet

9. References/ source documents

Women and HIV in the United Kingdom Data to end of December 2017”PHE https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/912615/Women_and_HIV_in_the_UK_2017.pdf

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Guidelines for the Management of HIV in Pregnancy and Postpartum 2018 (2020 third interim update) - **https://www.bhiva.org/pregnancy-guidelines**

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Epalza C, Goetghebuer T, Hainaut M *et al.* High incidence of invasive group B streptococcal infections in HIV-exposed uninfected infants. *Pediatrics* 2010; **126**: e631-638.

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Appendix 1: Drug dosing for infants (see BHIVA Guidelines)

<table>
<tr><th>DRUG</th><th>DOSE</th><th>COMMENTS/SIDE EFFECTS</th></tr>
<tr><td colspan="3">NRTIs: nucleoside reverse transcriptase inhibitors</td></tr>
<tr><td>Zidovudine
(ZDV) (Retrovir®)
Also known as azidothymidine (AZT)

Liquid – 10 mg/mL</td><td><u>Oral:</u>
<table>
<tr><th>Gestation +/- weight</th><th>Dose</th></tr>
<tr><td><30/40 gestation at birth</td><td>2 mg/kg twice a day</td></tr>
<tr><td>30–34/40 gestation at birth</td><td>2 mg/kg twice a day for 2/52 then 2 mg/kg three times a day</td></tr>
<tr><td>≥34/40 gestation at birth and ≤2 kg</td><td>4 mg/kg twice a day – round dose <u>up</u> to the nearest 0.5 mg to assist administration</td></tr>
<tr><td>≥34/40 gestation at birth and >2 kg</td><td>See dose banding table</td></tr>
</table>
<u>Duration oral dosing:</u>
• Very low risk monotherapy – 2 weeks
• Low risk monotherapy – 4 weeks
• Combination therapy – 4 weeks
<u>Intravenous:</u>
• ≥34/40 gestation – 1.5 mg/kg four times a day
• <34/40 gestation – 1.5 mg/kg twice a day, change to four times a day at 34/40</td><td>Anaemia, neutropenia
<table>
<tr><th>Weight range (kg)</th><th>Oral dose (equivalent to 4 mg/kg)
<u>TWICE A DAY</u></th><th>Volume to be given orally
<u>TWICE A DAY</u></th></tr>
<tr><td>2.01–2.12</td><td>8.5 mg</td><td>0.85 mL</td></tr>
<tr><td>2.13–2.25</td><td>9 mg</td><td>0.9 mL</td></tr>
<tr><td>2.26–2.37</td><td>9.5 mg</td><td>0.95 mL</td></tr>
<tr><td>2.38–2.50</td><td>10 mg</td><td>1 mL</td></tr>
<tr><td>2.51–2.75</td><td>11 mg</td><td>1.1 mL</td></tr>
<tr><td>2.76–3.00</td><td>12 mg</td><td>1.2 mL</td></tr>
<tr><td>3.01–3.25</td><td>13 mg</td><td>1.3 mL</td></tr>
<tr><td>3.26–3.50</td><td>14 mg</td><td>1.4 mL</td></tr>
<tr><td>3.51–3.75</td><td>15 mg</td><td>1.5 mL</td></tr>
<tr><td>3.76–4.00</td><td>16 mg</td><td>1.6 mL</td></tr>
<tr><td>4.01–4.25</td><td>17 mg</td><td>1.7 mL</td></tr>
<tr><td>4.26–4.50</td><td>18 mg</td><td>1.8 mL</td></tr>
<tr><td>4.51–4.75</td><td>19 mg</td><td>1.9 mL</td></tr>
<tr><td>4.76–5.00</td><td>20 mg</td><td>2 mL</td></tr>
</table></td></tr>
<tr><td>Lamivudine (3TC) (Epivir®)
Liquid 10 mg/mL</td><td><u>Oral:</u> usually as part of combination therapy
2 mg/kg twice a day – round dose <u>up</u> to nearest 0.5 mg to assist administration</td><td>Anaemia, neutropenia
(much less common than with ZDV)</td></tr>
<tr><td>Abacavir (ABC) (Ziagen®)
Liquid 20 mg/mL</td><td><u>Oral:</u> usually as part of combination therapy
2 mg/kg twice a day– round dose <u>up</u> to nearest 1 mg to assist administration</td><td>Hypersensitivity reactions have not been noted in neonates</td></tr>
<tr><td>Tenofovir
(TDF) (Viread®)
245 mg tenofovir disoproxil = 300 mg TDF</td><td><u>Oral:</u> usually as part of combination therapy
All doses now based on tenofovir disoproxil salt (TD)
(*245 mg TD tablet dissolved in 24.5 mL water gives 10 mg/mL)
4.9 mg/kg (0.49 mL/kg*) once a day (round dose <u>up</u> to the nearest 0.5 mg (<10 mg) or 1 mg (≥10 mg) to assist administration)</td><td>Renal dysfunction: consider monitoring renal function weekly</td></tr>
<tr><td colspan="3">NNRTI: non-nucleoside reverse transcriptase inhibitor</td></tr>
</table>

<table>
<tr><td>Nevirapine (NVP) (Viramune®)

Liquid 10 mg/mL</td><td><u>Oral:</u> usually as part of combination therapy
2 mg/kg once a day for 1 week, then 4 mg/kg once a day for 1 week – round doses <u>up</u> to the nearest 0.5 mg to assist administration
If mother has already received >3 days of nevirapine:
4 mg/kg once a day – (round doses <u>up</u> to the nearest 0.5 mg)</td><td>Rash and liver dysfunction – rare in neonates
Stop NVP after 2/52, in view of long half-life, continue other PEP agents for full 4/52</td></tr>
<tr><td colspan="3">INSTI: integrase strand transfer inhibitor</td></tr>
<tr><td>Raltegravir
(RAL) (Isentress®)
100 mg sachets for oral suspension (10 mg/mL)</td><td><u>Oral:</u> usually as part of combination therapy
1.5 mg/kg once a day from birth to day 7, then 3 mg/kg twice a day until 4 weeks of age. See dose banding:
<table><tr><th>Body weight (kg)</th><th>Dose</th></tr><tr><td colspan="2">In full-term neonates >37 weeks</td></tr><tr><td colspan="2">Birth to 1 week – once a day dosing</td></tr><tr><td>2 to <3 kg</td><td>4 mg once a day</td></tr><tr><td>3 to <4 kg</td><td>5 mg once a day</td></tr><tr><td>4 to <5 kg</td><td>7 mg once a day</td></tr><tr><td colspan="2">1 to 4 weeks – twice a day dosing</td></tr><tr><td>2 to <3 kg</td><td>8 mg twice a day</td></tr><tr><td>3 to <4 kg</td><td>10 mg twice a day</td></tr><tr><td>4 to <5 kg</td><td>15 mg twice a day</td></tr></table></td><td>Rash and liver dysfunction: monitor liver function tests at 5–7 days of age</td></tr>
<tr><td colspan="3">PI - protease inhibitor</td></tr>
<tr><td>Lopinavir/ritonavir
(Kaletra®)
Liquid:
5 mL = (Lopinavir 400 mg + ritonavir 100 mg)</td><td><u>Oral:</u> usually as part of combination therapy
300 mg/m² (of lopinavir) twice a day – use dose banding table below
<table><tr><th>Weight range (kg)</th><th>SA range (m²)</th><th>Kaletra volume to be given orally <u>TWICE A DAY</u></th></tr><tr><td>1–1.5</td><td>0.1–0.13</td><td>0.5 mL</td></tr><tr><td>1.51–2</td><td>0.14–0.16</td><td>0.6 mL</td></tr><tr><td>2.01–2.5</td><td>0.17–0.19</td><td>0.75 mL</td></tr><tr><td>2.51–3</td><td>0.20–0.21</td><td>0.8 mL</td></tr><tr><td>3.01–3.5</td><td>0.22–0.24</td><td>0.9 mL</td></tr><tr><td>3.51–4</td><td>0.25–0.26</td><td>1 mL</td></tr><tr><td>4.01–4.5</td><td>0.27–0.28</td><td>1.1 mL</td></tr><tr><td>4.51–5</td><td>0.29–0.30</td><td>1.2 mL</td></tr></table></td><td>Severe adrenal dysfunction, electrolyte imbalance and cardiogenic shock in neonates, especially premature infants
Avoid in premature infants, only use, as per birth plan, when benefit of giving outweighs the potential risks
Monitor for signs of toxicity, check U+E, pH, glucose, lactate, LFT, daily for first 5 days</td></tr>
<tr><td colspan="3">FI: fusion inhibitor</td></tr>
<tr><td>Enfuvirtide
(Fuzeon®)
(T-20)</td><td><u>Intravenous:</u> usually as part of combination therapy
2 mg/kg IV twice a day (as infusion over 30 minutes)
Method: To reconstitute the 108 mg vial slowly add 1.1 mL of water for injections from the vial of diluent provided to the vial of enfuvirtide powder, do not shake or invert the vial. The powder will</td><td>Experimental IV dosing regime
Use only, as per birth plan, when benefit of giving outweighs the potential risks</td></tr>
</table>

	take up to 45 minutes to dissolve. The resulting solution contains 90 mg in 1 mL. Add 1 mL (90 mg) of the solution to 10 mL of water for injections, then further dilute to 45 mL with water for injections, do not shake or invert the syringe. The final solution contains 90 mg in 45 mL (2 mg in 1 mL) from which to administer the required dose	
PCP prophylaxis		
Co-trimoxazole (Septrin®) 240 mg in 5 mL liquid	**BW ≥2 kg** 120 mg = 2.5 mL **BW <2 kg** 60 mg = 1.25 mL ONCE a day on 3 days per week	Only HIV-infected infants, start at 4 weeks of age. May rarely cause rash and bone marrow suppression