HIV Antenatal and Perinatal Management of Women Known to be HIV Positive and their Infants

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Guideline to be followed by (target staff): All healthcare professionals involved in the screening and management of HIV in pregnancy and care of the newborn

To be read in conjunction with the following documents:

- Screening in Pregnancy guideline
- Perinatal Retrovirus Infection Care Plan

Are there any eCARE implications? No

CQC Fundamental standards:

Regulation 9 – person centred care
Regulation 10 – dignity and respect
Regulation 11 – Need for consent
Regulation 12 – Safe care and treatment
Regulation 13 – Safeguarding service users from abuse and improper treatment
Regulation 14 – Meeting nutritional and hydration needs
Regulation 15 – Premises and equipment
Regulation 16 – Receiving and acting on complaints
Regulation 17 – Good governance
Regulation 18 – Staffing
Regulation 19 – Fit and proper

Disclaimer

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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Guideline Statement

To enable staff to care for women known to be HIV positive and their infants.

Executive Summary

The guideline has been developed in response to the new recommendations from the British HIV Association (BHIVA) guidelines published in 2018 with third interim update in 2020. Milton Keynes University Hospital NHS Foundation Trust has also developed a multi-disciplinary group in order to plan, co-ordinate and manage individual care; working together to develop, monitor and audit standards.

Most HIV infected children in this country have acquired the infection from their mothers (vertical transmission). There are now interventions that can reduce the risk of mother to child transmission of HIV from 25% to less than 1%. In order for women to take full advantage of these, it is vital to diagnose the infection before they give birth.

The Department of Health recommends that all pregnant women are offered and recommended HIV testing as an integral part of their antenatal care. The 2003 Department of Health's Screening for Infectious Diseases in Pregnancy Standards set a target of 90% for the uptake of antenatal screening for HIV. The 2010 revised Standards retained this 90% uptake target but expanded this to include HIV, Hepatitis B, syphilis and rubella. Based on 2014/15 HIV Key Performance Indicator data thresholds for coverage data has been revised to ≥95% acceptable and ≥99% achievable from April 2016. Antenatal screening for rubella susceptibility ceased on 1st April 2016 and is no longer offered to pregnant women.

In 2015 uptake of screening for all infections remained high (>97%). In 2015 27% (543/2,003) of diagnosed HIV-positive pregnant women were identified as a result of antenatal screening in their current pregnancy. In England in 2015 0.15% (1,082/720,590) of pregnant women screened positive or were reported already known to have HIV.

The main aim of this guideline is to ensure a high standard of care is achieved and maintained for those women who are HIV positive, to prevent the transmission of HIV to their infants.

The key aspects of perinatal management of HIV infection in pregnant women to minimise vertical transmission are:

- **Antenatal diagnosis of HIV**
- **Pre-labour caesarean section at 38-39 weeks gestation or safe vaginal delivery.**
- **Intravenous (IV) Zidovudine administration to mothers during delivery if HIV viral load is not adequately suppressed.**
- **Oral or IV ART post-exposure prophylaxis (PEP) to the neonate for 2-4 weeks depending on the risk assessment.**
- **Recommend that women living with HIV feed their babies with formula milk**

Abbreviations

MTCT: Mother to child transmission
PROM: premature rupture of membranes
PEP: Post-exposure prophylaxis
ARM: artificial rupture of membranes
ART: Antiretroviral treatment

HIV: Human Immunodeficiency Virus
DNA: Deoxyribonucleic acid
PCR: Polymerase Chain Reaction
FBC: Full Blood Count
LFT: Liver Function Tests
U&E: Urea and Electrolytes
BBV: Blood borne virus
PCP: Pneumocystis Carinii Pneumonia

1.0 Roles and Responsibilities – Screen Positive HIV Result:

1.1 Antenatal and Newborn Screening

The Antenatal and Newborn Screening midwives are notified via generic email (mkg-tr.mkscreeningmidwives@nhs.net) by the microbiology team of any rejected samples, samples sent to the confirmation laboratory and screen positive results for HIV screening. Any rejected samples are followed-up by the screening midwives, and repeat samples requested. The microbiology department will follow-up with the screening team any repeat samples that are not received via the generic email.

(see Standard Operating Procedure: Antenatal and Newborn Failsafe and Tracking Processes)

On receipt of a confirmed screen positive HIV result, the Antenatal and Newborn screening team contact the BBV nurse to arrange a joint appointment to see the patient in order to give the results, counsel regarding HIV diagnosis and discuss interventions to reduce mother to child transmission.

Women should be seen as per Standard 5: ≤ 10 working days of the screen positive result being received by the screening team or notified to the screening team of any known HIV positive woman.

Initiate a baby alert form and send to the lead Neonatal Consultant and the lead Paediatric Consultant for HIV.

Ensure that Obstetric care is with the lead Consultant for HIV and that an appointment is made for 24/40 gestation or earlier if there are other obstetric risk factors present, in order to develop individualised care plan for the woman.Lead HIV nurse co-ordinates appointments with the obstetric team – or will find out when obstetric appointments are and try and coordinate one of HIV team to attend.

1.2 BBV/HIV department

Initial assessment should be facilitated as soon as possible following HIV diagnosis in pregnancy or when pregnancy is confirmed in a known HIV positive woman.

Pregnant women who are newly diagnosed with HIV: the lead HIV nurse will expedite referral to BBV/HIV Consultant, ideally for the same day as when results to be given to the patient, for full medical assessment and to establish if HIV symptomatic or asymptomatic. HIV nurse will undertake baseline HIV investigations to include: CD4 count, Viral Load, resistance and full sexual health screen (to include Hepatitis B & C and Syphilis).

Pregnant women diagnosed with HIV prior to pregnancy: the lead HIV nurse will arrange review by BBV/HIV consultant when informed of pregnancy and liaise with woman and midwifery team to

arrange booking appointment. Women who conceive on effective ART and have an undetectable HIV viral load should stay on their current regime until they are reviewed by BBV/HIV consultant.

Summary of Use of ART in Pregnancy: Conceiving on ART

Conceiving Whilst on ART: It is recommended that women conceiving on an effective ART regimen should continue this treatment.
Exceptions are:

- Non-standard regimens, for example PI monotherapy
- Regimens that have been demonstrated to show lower pharmacokinetics in pregnancy such as darunavir/cobicistat and elvitegravir/cobicistat
- Where there is an absence of pharmacokinetic data such as raltegravir 1200 mg once daily (od) (should be administered 400 mg twice daily [bd]).

These should be modified to include (depending on tolerability, resistance, and prior antiretroviral history) one or more agents that cross the placenta.

Conceiving Whilst on Dolutegravir:

- A woman planning a pregnancy and/or conceiving on dolutegravir should see her HIV physician as soon as possible to discuss current evidence on neural tube defects.
- Women taking dolutegravir who are trying to conceive or in the first trimester of pregnancy (<12 weeks gestation) should be recommended to take Folic Acid 5mg Daily

Folic Acid:

- Women on regimens that do not contain dolutegravir should take the standard recommended dose of folic acid 400 μg once daily, unless they meet the criteria for a higher dose of folic acid.
- It is recommended that all women start folic acid supplementation before pregnancy and continue to 12 weeks' gestation (the end of the first trimester).

Recommended and alternative agents in pregnancy:

Nucleoside backbone combinations recommended by BHIVA for HIV in pregnancy include tenofovir DF/emtricitabine and abacavir/lamivudine. Pregnant women may also want to consider zidovudine/lamivudine [1]. Considerations for the backbone include side-effect profile, frequency of dosing, interactions with the third agent, adverse outcome profiles and prior ART experience including a resistance profile where available. Women are advised against the combination of tenofovir DF/emtricitabine and lopinavir/r (especially high-dose lopinavir/r), which demonstrated an increased risk of neonatal death and prematurity in the randomised controlled PROMISE trial.

Type of Antiretroviral	Preparation	Alternative
Nucleoside reverse transcriptase inhibitor (NRTI) backbone	Women are recommended to start • tenofovir DF with emtricitabine • abacavir with lamivudine	Tenofovir alafenamide/ emtricitabine (after the first trimester) Zidovudine/lamivudine
Third Agent It is recommended that an integrase inhibitor-based regimen be considered as the third agent of choice in patients:	Efavirenz Atazanavir These are agents with the most safety data in pregnancy.	Rilpivirine 25mg daily Darunavir (600/100 mg bd) if known resistance, and consideration should be given to using this higher dose if

• With high baseline viral load (>100,000 HIV RNA copies/mL) • Where ART is failing to suppress the virus.		darunavir is initiated in pregnancy. Raltegravir 400 mg bd. Raltegravir 1,200mg Daily should NOT be used. Dolutegravir 50mg daily (after 8 weeks' gestation – which must be confirmed by scan)
Zidovudine monotherapy is not recommended and should only be used in women declining ART with a viral load of < 10,000 HIV RNA copies/mL and willing to have a caesarean section (CS).		
Dolutegravir is not recommended until after 8 weeks gestation (confirmed by scan) due to reports of increased risk of neural tube defects among infants of women who became pregnant whilst taking Dolutegravir based regimens.		
There is insufficient data on first trimester exposure to determine teratogenic risk for Etravirine and Maraviroc.		
Nevirapine is no longer recommended as a componenet of ART for pregnant women. A single dose may be given (regardless of CD4 count) during labour or to cover any invasive intrauterine procedure.		
Tenofovir alafenamide may be prescribed for women after the first trimester of pregnancy.		
PI monotherapy, triple nucloside regimens, and Cobistat boosted regimens like darunavir/cobicistat, atazanavir/cobistat, and elvitegravir/cobicistat are not recommended in pregnancy		
Atazanavir is recommended over Darunavir and Lopinavir which have an increased risk of pre-term delivery. Bilirubin should be monitored with Atazanavir due to risk of maternal hyper-bilirubinaemia. There is no risk of kernicterus. Atazanavir should not be used unboosted.		

Woman is not already on ART: - when to start:
All pregnant women should start ART during pregnancy and be advised to continue lifelong treatment.

Current BHIVA treatment guidelines recommend treatment of all people living with HIV, regardless of CD4 cell count or clinical status. Studies have shown that immediate initiation of ART improves clinical outcomes for patients, regardless of initial CD4 cell count, and reduces transmission of HIV among sero-discordant partners if the partner with HIV has an undetectable HIV viral load on ART. All pregnant women living with HIV should be counselled about the importance of continuation of ART postpartum. Major determinants of a woman suppressing to a viral load < 50 HIV RNA copies/ml by the time of delivery are the baseline untreated viral load and the time available to achieve this target. In both the UK and Ireland, and also the ANRS French Perinatal Cohort, vertical transmission was significantly associated with starting treatment later in pregnancy.

Managing the Risks and Complications of Treatment:

- Initiating ART may cause nausea and/or vomiting. This should be managed conservatively with Cyclizine or Promethazine. The ability to maintain absorption of ART without vomiting must be assessed.
- Where treatment failure may occur due to severe hyper-emesis gravidarum – aggressively manage hyper-emesis and potentially discuss at a HIV MDT meetings.
- Consider ART induced lactic acidosis if any woman presents with vomiting, malaise, oedema, abdominal pain, and raised transaminases.

- Regular monitoring of LFTs must occur as abnormal LFTs could be due to ART, obstetric cholestasis, pre-eclampsia, HELLP syndrome, and fatty liver.
- Tenofovir renal toxicity can cause proteinuria. If accompanied by glycosuria – consider Fanconi syndrome. Alternative diagnoses include UTIs or pre-eclampsia.
- If patient presents with Glycosuria – consider Fanconi syndrome if patient on Tenofovir. Alternative diagnoses include gestational diabetes.

Late-presenting woman not on treatment

A woman who presents after 28 weeks should commence ART without delay.
If the viral load is unknown or >100,000 HIV RNA copies/mL, a three- or four-drug regimen that includes Raltegravir 400 mg bd or dolutegravir 50 mg od is suggested
Management of an untreated woman presenting in labour at term. All women should be given a stat dose of nevirapine 200 mg; and commence oral zidovudine 300 mg and lamivudine 150 mg bd; and Raltegravir 400 mg bd; and receive intravenous zidovudine for the duration of labour.
In preterm labour, if the infant is unlikely to be able to absorb oral medications consider the addition of double-dose tenofovir DF to the treatment to further load the infant.
Women presenting in labour/with spontaneous rupture of the membranes (SROM)/requiring delivery without a documented HIV result must be advised to have an urgent HIV test. A reactive/positive result must be acted upon immediately, with initiation of interventions to prevent vertical transmission of HIV without waiting for further/formal serological confirmation.

Establish consent and encourage disclosure of HIV status to health care professionals involved in care and documenting in as HIV infection – to ensure clarity as T4 cell disorder has been misinterpreted in past as thyroid disorder – It has been used historically as concern over inadvertent disclosure in hand held notes to family etc. and confidentiality – but using alternative names exacerbates stigma and can be misinterpreted.

Discuss and encourage disclosure to partner to enable partner testing and contact tracing/testing.

Discuss, encourage and facilitate testing of existing children.

Discuss risk of transmission to baby and the benefits of anti-retroviral medication during pregnancy and birth, together with their possible side-effects. Antiretroviral therapy will normally be started before 24 weeks if not currently taking any. The choice of antiretroviral therapy for women commencing treatment in pregnancy should be in line with current BHIVA guidelines for the management of HIV positive patients and should be informed by HIV genotypic resistance testing, hepatitis coinfection, previous antiretroviral therapy (ART), adherence considerations and maternal choice.

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. We therefore continue to recommend that women living with HIV feed their babies with formula milk. However women who are virologically suppressed on ART with good adherence and who choose to breastfeed should be supported to do so, but should be informed about the low risk of transmission of HIV through breastfeeding in this situation and the requirement for extra maternal and infant clinical monitoring.

When a woman decides to breastfeed, she and her infant should be reviewed monthly in HIV clinic for HIV RNA viral load testing during and for 2 months after stopping breastfeeding. Maternal ART (rather than infant pre-exposure prophylaxis [PrEP]) is advised to minimise HIV transmission through breastfeeding and safeguard the woman's health.

Discuss methods of lactation suppression – offer option of stat dose Carbergoline (1mg) postnatally if chooses to use artificial feeding.

In women on antiretroviral therapy in pregnancy a viral load should be performed 2–4 weeks after commencing antiretroviral therapy, at least once every trimester, at 36 weeks and at birth and updated in care plan.

Screening for genital tract infections including evidence of BV should be done as early as possible in pregnancy and consideration should be given to repeating this at around 28 weeks.
Syphilis serology should be performed on both occasions.

1.3 Lead Obstetric Consultant

Initial appointment at 24/40 gestation, or earlier if there are other obstetric risk factors present,in order to develop individualised care plan for the women.

Please see section 3.2 of guideline (Obstetric Management) for a detailed management of various antenatal and Intrapartum scenarios. A final birth care plan will be filed in the mother's care plan.

Prescribe anti-retroviral therapy for intrapartum care if maternal viral load is over 50 copies/ml, as then zidovudine IV infusion for the pregnant woman will be required, and ensure prescription chart is sent to pharmacy, for medication to be stored on Labour Ward (see appendix 4).

Intrapartum Zidovudine:

- Intrapartum IV Zidovudine is required if the most recent maternal HIV virus load is > 1,000 copies/ml or is unknown.
- Commence at onset of labour or 4 hours before PLCS and continue until umbilical cord clamped. Do not delay caesarean section to complete IV Zidovudine if patient is in labour or if amniotic membranes have ruptured.
- Intrapartum IV Zidovudine is not recommended if most recent maternal viral load is between 50 and 1,000 copies/ml, but can be considered.
- Clinically IV Zidovudine may be maintained if patient presents with Zidovudine monotherapy

New HIV Diagnosis Presenting at Labour:

- Have urgent testing for HIV.
- If test is positive, a confirmatory test needs to occur, but all women should be commenced on the following to prevent vertical transmission pending formal serological diagnosis of HIV.
    - Stat dose Nevirapine
    - If pre-term, consider stat oral double dose of Tenofovir DF.
    - Start Zidovudine 300mg BD and Lamivudine 150mg BD and Raltegravir 400mg BD
    - Administer IV Zidovudine for the duration of labour.
    - Infant to receive combination of post-exposure prophylaxis.
    - ART continues through the delivery period and into the post-natal period. No ART medication should be discontinued unless there is a significant clinical reason.

1.4 Labour ward Doctors/Midwives

Care is consultant led care between HIV and obstetric team – hand over is via discharge summary and clinic letters to the GP and patient.

Please see section 3.2 (Obstetric Management) of this guideline for detailed discussion.

Follow care pathway unless otherwise indicated with regards to medication regime.

Ensure mother takes her usual medication throughout labour.

Prescribe appropriate peri-operative antibiotics for all LSCS and PROM.

Inform Paediatricians of mother's admission to Labour ward in established labour/Elective LSCS.

Screening team is not informed if positive patient has given birth – midwives follow guidance in care plan. Baby is weighed at birth – then midwife calls the paediatric team to prescribe baby medications and these are to be given within 4 hours

Following birth, wash the baby as soon as possible, prior to giving IM vitamin K.

Weigh baby immediately after birth and inform the Paediatric SHO, so that drugs required can be prescribed quickly on an infant drug chart and sent urgently to pharmacy. For out of hours: the Site Manager must be bleeped (1222) to access the Emergency Pharmacy Drug Cupboard (PEC) in pharmacy.

Ensure neonate commences anti-retroviral medication within 4 hours after birth.

Ensure PAIRED blood samples taken - Blood samples are taken after birth:

- Midwife to obtain sample from the mother
- HIV DNA PCR ("Pro Viral HIV" on eCare) - Obtain 2x4ml EDTA sample (lavender top)
- HIV viral load - Obtain a further 2x4ml EDTA sample (lavender top)
- Midwife to ensure paediatricians obtain sample from the baby, Label the PCR samples and forms with both the mother's and baby's details. Send both mother and neonatal PCR samples together.

Breastfeeding discussed antenatally as per paragraph on page 7 and a clear plan documented about mother's decision will be documented in patient notes.
If formula feeding - discuss lactation suppression and administer cabergoline 1mg post-birth for suppression of lactation if mother has agreed in the care plan with consent.

Ensure that prior to discharge, the mother knows how and when to administer neonatal medication (Please see Appendices 5 and 6 for dosing regimens).

Ensure Paediatric Team have arranged follow-up:

- with Paediatric Consultant Lead for HIV 6-8 weeks post discharge for neonate.
- with Paediatric Day Care Unit when neonate 6 weeks old for further blood samples for HIV DNA PCR ("Pro Viral HIV" on eCare), FBC, LFT and U&E's. Inform lead HIV nurse (mobile 07770 643214) of date so a 6 week BBV/HIV appointment can be arranged to coincide

1.6 Paediatricians

Find baby alert either in the folder on the neonatal unit or on Labour Ward. If no baby alert found, discuss with Neonatal Consultant of the week.

Once baby has been weighed, prescribe antiretroviral drugs as soon as possible and send to pharmacy urgently so that anti-retroviral therapy can be dispensed and given to baby within 4 hours of birth. If baby is born out of hours, bleep the Site Manager on Duty for access to the Emergency Drug cupboard.

PAIRED blood samples - Blood samples are taken after birth:

- Ensure neonatal bloods are taken within 48 hours of birth and prior to discharge home (N.B. **not** cord blood) for HIV DNA PCR ("Pro Viral HIV" on eCare) in a 2ml EDTA bottle and send to microbiology with maternal blood. Also send a blood sample for LFT, U&Es and FBC.
- Midwife to obtain sample from the mother: HIV DNA PCR Obtain 2x4ml EDTA sample (lavender top) and HIV viral load obtain further 2x4ml EDTA sample (lavender top)
- Label the PCR samples and forms with both the mother's and baby's details.
- Send both mother and neonatal PCR samples together.
- Assess the mothers Hepatitis B status - Neonatal immunization with or without HBIG should commence within 24 hours of birth in accordance with the hepatitis B guideline and Baby alert if available.

- Arrange a 6-8 week follow up appointment with the Paediatric Consultant Lead for HIV.
- Arrange a 6 week appointment in Paediatric Day Care Unit to obtain blood samples for HIV DNA PCR ("Pro Viral HIV" on eCare), FBC, LFT and U&E's
- Inform lead HIV nurse of date (mobile 07770 643214) so a 6 week BBV/HIV appointment can be arranged to coincide so that the bloods are sent off together.
- Arrange a 12 week appointment in Paediatric Day Care Unit for repeat HIV DNA PCR blood test ("Pro Viral HIV" on eCare).
- If this sample negative, liaise with TB Nursing service for BCG vaccine if not already vaccinated.

BCG can be given in most cases unless maternal viral load can be detected.

Arrange final HIV DNA PCR blood test ("Pro Viral HIV" on eCare) for 18 months. If, BCG vaccine has not already been given, recommend and arrange.

1.7 Lead Paediatric Nurse

Inform the mother and GP (if mother has consented) by letter of each set of results in a timely manner to reduce unnecessary anxiety.

2.0 Implementation and dissemination of document

This guideline will be uploaded onto the intranet.

3.0 Processes and procedures

3.1 Antenatal care

Prompt referral should be made between antenatal screening team (ANNBS), the obstetrician, HIV physician and clinical nurse specialist. A multidisciplinary team approach and communication between all parties involved must be seamless. Central to this are copies of clinic letters, communication of HIV Viral Load results (particularly during the third trimester) and the *Perinatal Care Plan*

If, new antenatal HIV diagnosis, undertake HIV serology and discussion of diagnosis. Screening team/midwives to liaise with HIV team to give results to the patient in the presence of the HIV Team, within the antenatal clinic setting. Women should be seen as per Standard 5: ≤ 10 working days of the screen positive result being received by the screening team or notified to the screening team of any known HIV positive woman.

HIV team do this for all patients newly diagnosed with HIV antenatally and explains what happens post diagnosis of HIV.

Confidentiality /disclosure issues discussed *and documented*

- Arrangements for testing partner/previous children and safer sex advice
- Baseline bloods & serology: U&E, LFTs, FBC, glucose, Hepatitis A, B & C, CMV, toxoplasma, syphilis
- Initial CD4 and HIV VL, (HIV viral load minimum once every trimester and at 36 weeks)
- Initial STI screen in GUM (including Bacterial Vaginosis), repeat at 28/40 gestation if required
- Initial physical examination in relation to HIV disease and pertinent investigations
- Relevant printed information given following appropriate discussion, psycho-social support if required
- Antiretroviral therapy (ARV) planned, discussed and documented; adherence reinforced.
- Inform multidisciplinary team: paediatrician, midwife, obstetrician, HIV physician, (and GP if the patient consents), other teams as appropriate. Screening midwives are copied in the clinic letter HIV clinic letter as are paediatricians and obstetric team.
- **CARE PLAN commenced and updated regularly with viral loads and CD4 count**
- HIV viral load should be undetectable (<50 copies/ml) at birth, ideally by 36 weeks gestation
- Fetal ultrasound imaging should be performed as per national guidelines regardless of maternal HIV status. It may be indicated if other risk factors are present
- Mother should be advised to bring her HIV medications into hospital with her – care should be taken not to miss doses of antiretrovirals around and following birth

- Ongoing management of the HIV disease during and following pregnancy in the mother, including relevant monitoring for adverse drug effects.

- document plans for infant feeding. If formula feeding offer lactate suppression with carbergoline 1mg stat post-birth.
- Discuss post-partum contraception, taking drug-drug interactions between antiretroviral therapy and hormonal contraception into consideration

3.2 Obstetric Management

- For women taking antiretroviral therapy, a decision regarding recommended mode of birth should be made after review of plasma viral load results at 36 weeks.
- A final birth care plan will be filed in the perinatal care plan kept on labour ward.
- The woman may have further questions at the time of labour and birth and may wish to change her mind regarding any intervention. Any discussion should be documented carefully and the mother's views respected.
- A maternal sample for plasma HIV viral load and HIV DNA PCR should be taken at birth.
- Women taking antiretroviral therapy should have their medications prescribed and administered before birth and, if indicated, after birth.

3.2.1 Induction of Labour

- For women with a plasma viral load of < 50 HIV RNA copies/mL at 36 weeks, and in the absence of obstetric contraindications, a planned vaginal birth is recommended.
- There is no contraindication to membrane sweep or to the use of prostaglandins or ARM and use of syntocinon.
- Women with a detectable viral load and who decline caesarean section and who are admitted for induction of labour should commence the IV zidovudine infusion when labour becomes established or membranes rupture.

3.2.2 Elective caesarean section

- Birth by elective caesarean section for obstetric indications should be delayed until after 39 completed weeks of gestation in women, with plasma viral loads of less than 50 copies/ml; to reduce the risk of transient tachypnoea of the newborn.
- Where the indication for caesarean section is the prevention of MTCT, caesarean section should be undertaken at between 38 and 39 weeks' gestation.
- For women with a plasma viral load of 50–399 HIV RNA copies/mL at 36 weeks, caesarean section should be considered, taking into account the actual viral load, the trajectory of the viral load, length of time on treatment, adherence issues, obstetric factors and the woman's views.
- Where the viral load is ≥ 400 HIV RNA copies/mL at 36 weeks, caesarean section is recommended.
- If intravenous zidovudine is indicated, the infusion should be started 4 hours before beginning the caesarean section and should continue until the umbilical cord has been clamped.
- Intrapartum intravenous zidovudine guidance is at Appendix 4
- The surgical field should be kept as haemostatic as possible and care should be taken to avoid rupturing the membranes until the head is delivered through the surgical incision.
- Peripartum antibiotics should be administered in accordance with national guidelines for the general population.

3.2.3 Planned vaginal birth

- Planned vaginal birth should only be offered to women taking antiretroviral therapy who have a viral load of less than 50 copies/ml.

- When a woman presents in labour, her plan of care for birth should be reviewed by the oncall obstetric team and recent viral load results should be confirmed as less than 50 copies/ml.
- In women for whom a vaginal birth has been recommended and labour has commenced obstetric management should follow the same guidelines as for the uninfected population
- Invasive procedures such as fetal blood sampling and fetal scalp electrodes are contraindicated.
- Whenever possible, for a woman with a detectable viral load, start zidovudine infusion 1 hr before ARM. If viral load is undetectable invasive procedures can be considered.
- If labour progress is normal, amniotomy should be avoided unless birth is imminent.
- Amniotomy and possible use of oxytocin may be considered for augmentation of labour.
- If instrumental birth is indicated, low-cavity forceps are preferable to ventouse and preferably be conducted by the most senior obstetrician present.

3.2.4 HIV Positive Women with Undetectable HIV Viral Load (<50 copies/ml)

- Unless the mother is on zidovudine monotherapy during the antenatal period, IV zidovudine is not required for women with an undetectable viral load at 36 weeks' gestation regardless of the mode of birth.

3.2.5 HIV Positive Women with Detectable HIV Viral Load (>50 copies/ml)

- If there have been adherence issues or a woman has not accessed services, commence IV zidovudine to be infused for the duration of labour and birth and order an urgent viral load on admission.
- Commence a three or four drug regimen that includes zidovudine 300mg BD and Lamivudine 150mg BD and Raltegrovir 400mg BD.
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- Consider giving stat dose Nevirapine 200mg and if the pregnancy is pre-term and/or oral feeding of the baby may not be possible consider double dose Tenofovir (discuss with HIV consultant (working hours) or infectious disease team on call at Oxford.
- .
- A woman with a detectable viral load will require IV zidovudine and should have a pre-prepared prescription in her central file ready for birth.

3.2.6 Vaginal birth after caesarean section

- Vaginal birth after Caesarean section (VBAC) should be offered to women with a viral load < 50 HIV RNA copies/mL.

3.2.7 Preterm labour

- In threatened preterm labour, initial assessment is in accordance with guidelines for the general populations apply that is steroids or tocolysis, if necessary and a genital infection screen.
- For women in preterm labour, urgent advice should be sought from the HIV physicians and paediatricians about the choice of anti-retroviral therapy. Infants born below 32 weeks of gestation are at increased risk of HIV but may be unable to tolerate oral medication.

3.2.8 Preterm prelabour rupture of the membranes

- The management of preterm pre labour rupture of membranes (PPROM) at ≥ 34 weeks is the same as term ROM except women who are 34–37 weeks' gestation will require group B streptococcus prophylaxis in line with national guidelines.
- When PPROM occurs at < 34 weeks:
  a. Intramuscular steroids should be administered in accordance with national guidelines
  b. Virological control should be optimized
  c. There should be multidisciplinary discussion about the timing and mode of birth
- A genital infection screen should be undertaken.
- Oral erythromycin should be started in accordance with national guidelines and consideration should be given to starting intravenous broad-spectrum antibiotics.
- Evidence of chorioamnionitis and fetal distress are indications for prompt birth. In other cases, the multidisciplinary team discussion will consider the adequacy of maternal antiretroviral therapy, plasma viraemia and the presence of any other pregnancy or HIV-related comorbidities

3.2.9 Pre-labour rupture of the membranes at term

- In the case of pre labour rupture of the membranes at term, birth should be expedited
- If maternal HIV Viral Load is <50 copies/mL immediate induction of labour is recommended with a low threshold for treatment of intrapartum pyrexia
- If maternal HIV Viral Load is 50–999 copies/mL, immediate caesarean section should be considered, taking into account the actual viral load, the trajectory of the viral load, length of time on treatment, adherence issues, obstetric factors and the woman's views.
- If maternal HIV viral load is ≥1000 RNA copies/mL plasma, immediate caesarean section is recommended.

3.2.10 Women diagnosed in late pregnancy but before the onset of labour

- A woman who presents after 28 weeks should commence antiretroviral therapy without delay
- If the viral load is unknown or > 100 000 HIV RNA copies/mL a three or four drug regimen that includes raltegravir 400mg BDor Dolutegravir 50mg daily is suggested.
- In preterm labour, if the infant is unlikely to be able to absorb oral medications consider the addition of double-dose tenofovir to further load the baby.

3.2.11 Women diagnosed with HIV during labour

- Women presenting in labour/with rupture of membranes (ROM)/requiring birth without a documented HIV result must be recommended to have an urgent HIV test. A reactive/positive result must be acted upon immediately with initiation of the interventions for prevention of mother to child transmission (PMTCT) without waiting for further/formal serological confirmation.
- If weekday Midwives to telephone HIV team to do a HIV point of care test and alert screening midwives.
- If out of hours call microbiology advise blood taken for urgent HIV test in womenin labour of unknown HIV status.
- For women who are HIV positive who are diagnosed during labour, urgent advice should be sought from the HIV physicians regarding optimum treatment and birth should be by caesarean section unless imminent .
- An untreated woman presenting in labour at term should be given a stat dose of nevirapine 200mg and oral zidovudine 300mg with lamivudine 150mg BD and raltegravir400mg BD.

In pre-term labour – pre-term neonate unlikely to absorb oral medications – consider addition of double-dose Tenofivir DF to treatment regimen

- Where possible, birth should be timed to be at least 2 hours after administration of IV zidovudine and nevirapine.
- It is suggested that intravenous zidovudine be infused for the duration of labour and birth.
- A confirmatory test should be taken, together with samples for CD4 count, viral load and resistance testing.
- The paediatricians should be informed so that neonatal care can be planned

3.3 Postnatal care

3.3.1 Neonate

- Please fill and place last 2 pages of perinatal care plan into baby`s notes as a "Neonatal Care Plan"

- Clean the baby's skin before giving IM Vitamin K. Until the baby has been bathed, staff handling him/her should wear gloves. Staff should wear gloves and a plastic apron when attending to the cord, or taking blood samples according to local guideline.

- Inform the senior paediatrician that the baby has been born

- The baby should not be routinely admitted to the Neonatal Unit. This should only happen if there is a specific medical indication for special or intensive neonatal care. There is no need for routine paediatric attendance at birth

- Administer antiretroviral prophylaxis **within 4 hours**. Do not delay for blood sampling.

- Very low risk babies require Zidovudine single agent prophylaxis for 2 weeks

- **Low risk babies require Zidovudine single agent prophylaxis for 4 weeks**

- **High risk babies require Zidovudine and Lamivudine prophylaxis for a total of 4 weeks plus 2 weeks of Nevirapine**

- The paediatrician will be required to prescribe the medication. Prescribe doses in milligrams (mg) and in millilitres (ml).

- In most cases, the need for such treatment will have been recognised during pregnancy. A written management plan in the Baby Alert Folder should be available.

- Please see Appendices 6 & 7 for drugs and dosing required for baby depending on maternal viral load.

- Consider letting the mother have responsibility for giving treatment to her baby when on the postnatal ward. The mother should be confident in administration of the medication prior to discharge. Please ensure that the antiretroviral drugs are transferred with the baby from the labour ward

- IV zidovudine can be given to neonate if not tolerating orally

- Co-Trimoxazole prophylaxis for Pneumocystis Jiroveci Pneumonia (PCP) should be given to:
  - All HIV-infected infants.
  - Infants with an initial positive HIV DNA/RNA PCR test result (and continued until HIV infection has been excluded).

Infants born to HIV-positive mothers should follow the routine national primary immunisation schedule.

BCG can be given soon after birth to babies in the very low risk category. However, for babies at high risk of HIV infection (see care plan for babies in Appendix 2), BCG should be delayed until after negative HIV DNA PCR at 12 weeks of age.

Before discharge bloods must be taken from the baby. These bloods include

- HIV DNA PCR (2ml EDTA)
- FBC, LFTs and U&E
- Ensure a maternal EDTA sample is sent with the infant's sample.

3.4 Discharge home

- Prescribe the remaining course of anti-retroviral therapy for the baby on going home. (as maybe 14 or 28 days) – Paediatric team would prescribe

- Ensure the mother/father/carer knows when to give this - the times should be convenient to her (i.e. not 2 am). – midwives/pharmacist could do this

- Baby can be discharged when well & tolerating oral medications. (Consultant decision)

- Consultant Paediatrician report births to the British Paediatric Surveillance Unit (BPSU)

- Write a discharge letter to the paediatrician and ensure the initial paediatric follow-up appointment with the Paediatric Lead for HIV is arranged for 6 – 8 weeks of age. Ensure further 6 week and 12 week appointment made in Paediatric Day Care Unit to obtain further blood samples for HIV DNA PCR ("Pro Viral HIV" on eCare), FBC, LFT and U&E's and inform lead HIV nurse (mobile 07770 643214) of date so a 6 week BBV/HIV appointment can be arranged to coincide. Paeds do discharge letter and arrange follow up.

- Do not copy letter to GP unless mother agrees to this (See Care Plan)

3.4.1 Mother

- All health professionals directly involved with care of the baby or mother should know that mother is living with HIV infection.

- Maternal Blood sample for "HIV proviral DNA PCR" at same time as neonatal test, as per above. Maternal blood sample for HIV viral load taken at birth. Midwives to take mothers blood and liase with paediatric team so mothers blood can be sent with paediatric bloods.

- Ensure that doses of antiretrovirals are not missed- and if any have been omitted, it is better to give treatment straight away followed by ALL other scheduled doses, than to wait until the next prescribed dose

- Check if antiretroviral therapy is to be continued or stopped – this will be documented in the care plan

- Infant feeding plans will have been discussed antenatally. If formula feeding the mother should be offered carbergoline 1mg stat to suppress lactation – this should be given after birth within the first post-partum day.

- Ensure Contraceptive options are discussed (and effect of antiretroviral therapy on contraceptive options)

- Check that HIV Follow up organised by telephoning HIV nurse – mobile 07770 643214 (under no circumstances should the patient ever be at risk of running out of medication). Ward team should ensure this is done on discharge

3.5 Different scenario management

3.5.1 Women presenting late in pregnancy

Immediately commence antiretroviral medication and determine biological and immunological status.

3.5.2 Women presenting in labour at term -urgent blood sample for HIV testing, unconfirmed HIV positive.

This is really rare occurrence – but has happened –take urgent blood sample for HIV and inform laboratory, to expedite any intervention and to prevent mother to child transmission of HIV – ie critical situation where only have hours to make any interventions possible. Results will be available on the same day, providing a provisional serological test/result for HIV. There needs to be some thought given to women attending who have not had any antenatal care/ blood work taken.

- Do baseline bloods, CD4 count, viral load, viral genotype
- Commence antiretroviral therapy immediately with raltegravir and fixed-dose zidovudine and lamivudine
- Commence IV zidovudine
- Give single dose of Nevirapine 200mg orally
- Emergency Caesarean section 2 hours after oral Nevirapine
- 3 drug infant prophylaxis for baby at birth (see Appendix 5)

3.5.3 Threatened preterm labour +/- ruptured membranes

- High vaginal swab for bacteriology
- Group B streptococcus prophylaxis as per local guideline

- Intramuscular steroids as per local guideliine
- Establish viral load status
- Mode and Timing of birth as per multi-disciplinary team discussions
- Nevirapine and raltegravir should be included within the antiretroviral regimen for pregnant woman as they cross the placenta rapidly and if the infant is unlikely to be able to absorb oral medications consider the addition of double-dose tenofovir to further load the baby.

3.6 The Perinatal Retrovirus Infection Care Plan

Applies to all pregnant women living with HIV - it is under utilised and mainly HIV nurses complete and usually midwives call rather than seeking out information from the care plans – hence the need for it to go into Ecare – so easily visualised and instantly informative that the woman being seen is living with HIV infection and therefore needs appropriate care pathways to be followed

An **individual perinatal care plan** should be available for all pregnant women living with HIV. This care plan contains details of hospital record numbers -genitourinary medicine (GUM), obstetrics, hospital etc - medications (including antiretroviral) prescribed, relevant baseline investigations and information discussed, as well as details of disclosure of HIV status to the patient's family and GP. The planned mode of birth with the date for any caesarean section will also be documented. Names and contacts of key health care providers will be included.

The care plan should also be completed by the physician overseeing the management of HIV along with the Obstetrician. It should be regularly updated.

The care plan is only on the Labour Ward.

It should be emphasised that the Care Plan does not operate in lieu of clinic letters - the latter should be copied to all relevant teams involved in the management of the mother, with particular reference to the latest viral load as this will materially affect management of the birth and afterwards.

Please refer to the Perinatal Retrovirus Infection Care Plan (appendix 2) available in the 'Medical Records Forms' section of the Trust intranet.

3.7 Infection Control

3.7.1 Personal Protective Equipment (PPE)

There are no additional items of PPE required because the mother is carrying a blood-borne virus. Recommended PPE is in accordance with the **nature** of the procedure and should be described in detail in the hospital policy.

3.7.2 Inoculation injuries

Refer to the Trust's **Needlestick / Inoculation Injuries Policy**. Contact Occupational Health *immediately* during normal working hours or seek specialist advice (as per Trust policy) *without delay*. A risk assessment of the incident will be carried out to ascertain whether or not HIV Post Exposure Prophylaxis is required.

4.0 Statement of evidence/references

References:

Antenatal screening for infectious diseases in England: summary report for 2013, Public Health England, Health Protection report, Infection Report Volume 8 Number 43 Published on: 14 November 2014

British HIV Association guidelines for the management of HIV infection in pregnant women 2012 (2014 interim review)

Andrew J Pollard, Shelley Segal, Jackie Sherrard, Anne Edwards, Mary Anthony, Tim Peto, Mel Snelling and Pauline Hurley And Hermione Lyall (Version: 21/108) Paediatric and Adult Infectious Disease Guidelines: Prevention of perinatal transmission of HIV

Service specification no.15: NHS Infectious Diseases in Pregnancy Screening Programme. Public Health England

Slogrove AL et al. Towards a Universal Antiretroviral Regimen. Curr Opin HIV AIDS 2017 July; 12 (4): 359-368

Mersey, Cheshire, & North Wales HIV Managed Care Network Guidelines 2019

5.0 Governance

5.1 Document review history

Version number	Review date	Reviewed by	Changes made
5	**07/2020**		**Reviewed and updated**

5.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
Clare Woodward	Consultant Sexual Health/BBV	27.05.20	08.07.20	Included	yes
Erum Khan	Consultant Obstetrician & Gynae	27.05.20	08.07.20	Included	Yes
Anita Males	Antenatal & Newborn Screening Co-ordinator	27.07.20	19.08.20	Reviewed and updated	Yes
Deirdre Sheedy	Lead BBV Nurse	27.05.20	10.11.20	Included	Yes
Erica Puri	Audit & Guideline Midwife		10/11/20	Included	Yes
Lazarus Anguvaa	Consultant Paediatrician		10.11.20	Included	Yes
Quality Assurance Advisers – Antenatal & Newborn Screening	QA advisers	11.2019	13.05.20	Comments acknowledged and included	Yes
Registrars/SHO and Midwives					
Julie Cooper	Head of Midwifery	27.05.20	19.08.20	Comments acknowledged and included	Yes
Janice Styles	Matron for Community, ANC and ANNB Screening	27.05.20	19.08.20	Comments acknowledged and included	Yes
Manish Nathwani	Pharmacist Manager – Medicines Optimisation	19.08.20	10.11.20	Included	Yes

5.3 Audit and monitoring

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
a) Care Processes by auditing the standardised care plans b) Monitoring the outcomes of the pregnancy by means of the 18 month infant blood test	a) Auditing standardised care plans b) Infant blood results	HIV Lead Nurse Specialist, Midwife for Prenatal Screening, Paediatric Lead Nurse	Annually	a) Individual departmental Clinical Governance meetings • Sexual Health • Maternity • Paediatrics b) HIV MDT meetings

5.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

Equality Impact Assessment			
Division	Women and Children	Department	Maternity
Person completing the EqIA	Anita Males Antenatal & Newborn Screening Co-ordinator	Contact No.	01908 995236
Others involved:		Date of assessment:	21.12.2020
Existing policy/service		New policy/service	

Will patients, carers, the public or staff be affected by the policy/service?	Yes
If staff, how many/which groups will be affected?	All staff

Protected characteristic	Any impact?	Comments
Age	NO	Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff
Disability	NO	
Gender reassignment	NO	
Marriage and civil partnership	NO	
Pregnancy and maternity	NO	
Race	NO	
Religion or belief	NO	
Sex	NO	

Sexual orientation	NO	

What consultation method(s) have you carried out?			
Circulated to all relevant staff groups (maternity and paediatrics), approved at Guideline Group			
How are the changes/amendments to the policies/services communicated?			
Email, team meetings, intranet post			
What future actions need to be taken to overcome any barriers or discrimination?			
What?	Who will lead this?	Date of completion	Resources needed
Review date of EqIA	21st December 2023		

Appendix 1: Perinatal Retrovirus Infection Care Plan

The Perinatal Retrovirus Infection Care Plan can be found on the Trust intranet at the following pathway:

Forms> Maternity> Perinatal Retrovirus Infection Care Plan

Appendix 2: Baby Alert Proforma

BABY ALERT FOR MOTHERS WITH HIV

Copy of this form to be sent to: Paediatric HIV specialist, Neonatal Consultant, Labour Ward

<table>
<tr><td>Obstetric Consultant</td><td>Parity</td><td rowspan="3">Surname
Forename
DOB
Hospital no.
Or affix patient label</td></tr>
<tr><td>Community Midwife</td><td>EDD</td></tr>
<tr><td>Mother's Phone Number</td><td>GP</td></tr>
<tr><td colspan="3">Details of referral (to be completed by consultant obstetrician, please include as much detail as possible, use reverse if required):
Date of diagnosis:
Current antiretroviral therapy (including dose):
Are Blood Born Virus (BBV) clinic aware of the pregnancy?
Name of BBV consultant and nurse:
Recent viral load:
Any additional information</td></tr>
<tr><td colspan="3">Neonatal care plan (please complete a perinatal care plan required for all mothers and babies. Please circle the medication regime on the neonatal postnatal care plan on the reverse)
Level of risk (circle as appropriate, to be completed by consultant obstetrician, risk is based on viral load and maternal medication): very low risk/ low risk/ high risk</td></tr>
<tr><td colspan="2">When to inform the paediatricians:
Circle as appropriate, to be completed by a Paediatricians
Whenever the Mother is admitted to labour ward
Shortly before birth
As soon as baby is born
Between within 12 hours of birth of baby</td><td>Who to inform:
Paed SHO (bleep 1630)
Paed registrar (bleep 1631)
Paed consultant
NNU</td></tr>
<tr><td>Signed</td><td>Name</td><td>Date</td></tr>
</table>

Care plan for babies born to women with HIV infection in pregnancy

Birth Weight	Paed consultant	Surname Forename DOB Hospital No. *Or affix patient label*
Time of birth	Any further risk factors?	
Recent maternal viral load	Level of Risk	

1. Baby to be cleaned before IM vitamin K injection is given
2. Bleep paediatric team to inform of delivery
3. Baby to be started on oral antiretroviral prophylaxis as soon as possible and within 4 hours after birth in all cases. Should be stored on NNU, may need to bleep site manager to release emergency drugs. ***(To be prescribed antenatally to avoid delay in the postnatal period)***

Risk-Assessment for Selecting Infant Post-Exposure Prophylaxis – Amended table
Very low risk
Start baby on monotherapy with oral Zidovudine 4mg/kg BD for 14 days if all three of the following criteria are met: 1. The woman has been on combination antiretroviral therapy for longer than 10 weeks during pregnancy 2. Two documented maternal HIV viral loads <50 HIV RNA copies/ml during pregnancy at least 4 weeks apart 3. Maternal HIV viral load <50 HIV RNA copies/mL at or after 36 weeks
Low risk
Extend to 4 weeks of Zidovudine 4mg/kg/dose BD monotherapy if: 1. Maternal HIV Viral Load < 50 copies/ml at or after 36 weeks but other very low-risk criteria not fulfilled. 2. Infant is born prematurely <34 weeks but most recent maternal HIV viral load is <50 HIV RNA copies/ml
High risk
Use the following triple combination: • Zidovudline 4mg/kg/dose BD for 4 weeks • Lamivudine 2mg/kg/dose BD for 4 weeks • Nevirapine 2mg/kg/dose OD for 1 week, then nevirapine 4mg/kg dose for another 1 week (total of 2 weeks nevirapine) then STOP if 1. maternal birth HIV viral load is known to be or likely to be >50 HIV RNA copies/ml on day of birth 2. if uncertainty about recent maternal adherence to cART 3. if HIV viral load is not known 4. Maternal HIV diagnosis made after delivery and baby is less than 72 hours old.
• Oral Zidovudine should be commenced as soon as possible after birth and at least within 4 hours. • If unable to feed, give Zidovudine IV infusion. This should be changed to oral Zidovudine once enteral feeding is established. And completed as per risk assessment.

- If there is a history of maternal resistance to antiretroviral medications, seek expert advice from Paediatric Infectious Disease team at St. Mary's Hospital, Imperial College London via switchboard. If guidance not immediately available, commence standard three-drug.

1. All babies to have blood tests within 48 hours of birth (not cord samples and before discharge home) for HIV/DNA/PCR in a 2ml EDTA bottle and send to microbiology with maternal blood. Also send a blood sample for LFT's, U&Es and FBC
2. Midwife to obtain blood sample from mother for: HIV DNA, PCR, obtain 2x4ml EDTA sample (lavender top) and HIV viral load obtain further 2x4ml EDTA sample. Label PCR forms with maternal and neonatal details and send the samples together.
3. Complete referral form for Paediatric Day Care Unit (PDCU) to perform further blood tests for HIV DNA PCR, FBC, LFT and U&E's to be done at 6 and 12 weeks of age and HIV antibody test at 18months of age.
4. Ask the PDCU team via the referral form to liaise with adult HIV to ensure the bloods for HIV DNA PCR, FBC, LFT and U&E's are taken on the same day as the paediatric check up
5. Send a copy of this care plan to consultant paediatric HIV specialist once baby is born
6. OPD follow up with consultant paediatrician HIV specialist at 6-8 weeks.
7. Baby to be bottle fed, however if the mother wishes to breastfeed then she should be supported to do so. Offer carbergoline 1mg to Mother for milk suppression
8. Baby to have BCG vaccine at birth if very low risk or after 12 weeks if high risk
9. Discharge from hospital when above steps completed, baby is well and tolerating oral medications, mother is happy and she knows how to give the medications, when and for how long, documented in the maternal notes on eCare.

Appendix 3: Instructions for Intrapartum Zidovudine Infusion for pregnant women

National Guidelines recommend intrapartum zidovudine in the following circumstances:-

- For women with a viral load of > 1000 HIV RNA copies/mL plasma who present in labour, or with ruptured membranes or who are admitted for planned caesarean section.
- For untreated women presenting in labour or with ruptured membranes in whom the current viral load is not known.
- In women on zidovudine monotherapy undergoing a caesarean section intravenous zidovudine can be considered. Continued oral dosing is a reasonable alternative.
- For women on antiretroviral therapy with a viral load between 50 and 1000 HIV RNA copies/mL intravenous zidovudine can be considered regardless of mode of birth. However, continued oral dosing of their current regimen is a reasonable alternative.

Intrapartum Zidovudine Infusion

NB: Zidovudine Infusion and Oral Suspension are held in the Pharmacy Emergency Cupboard

Each 20ml vial contains 200mg Zidovudine. The final concentration for infusion must be 2mg/ml diluted with 5% Dextrose as follows:

- Withdraw 100ml of 5% Dextrose from 500ml bag.
- Add the contents of 5 vials of Zidovudine (1000mg in 100ml) to the 5% Dextrose bag above.
- Total volume is now 1000mg in 500ml or 2mg/ml.
- Once diluted, the infusion if stable for 24 hours.
- Any unused portion of the vial should be discarded.

Calculation of Infusion rate:

Loading dose of Zidovudine is 2mg/kg over one hour.

Continuous infusion 1mg/kg/hr.

E.g. for 80kg woman:

Loading dose of Zidovudine is 2mg/kg over one hour

2mg/kg or 1ml/kg = 80ml over one hour (160mg)

Continuous infusion 1mg/kg/hr

1mg/kg/hr or 0.5ml/kg/hr = 40ml/hr (80mg/hr)

Appendix 4: Neonatal Drug Doses

Neonatal Antiretroviral Therapy (ART) Post Exposure Prophylaxis (PEP) (from BHIVA Guidelines 2018) ***Please note that drug name abbreviations should never be used when prescribing***

<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 – 10mg/ml</td><td>Oral:
<table>
<tr><th>Gestation +/- Weight</th><th>Dose</th></tr>
<tr><td><30/40 gestation at birth</td><td>2mg/kg TWICE a day</td></tr>
<tr><td>≥ 30 to 30+6 /40 gestation at birth</td><td>2mg/kg TWICE a day for 2/52 then 2mg/kg THREE times a day</td></tr>
<tr><td>≥ 34/40 gestation at birth and ≤2kg</td><td>4mg/kg TWICE a day – round dose up to nearest 0.5mg to assist administration</td></tr>
<tr><td>≥ 34/40 gestation at birth and > 2kg</td><td>See dose banding table opposite</td></tr>
</table>
<u>Duration of oral dosing:</u>
• Very low risk monotherapy – 2 weeks
• Low risk monotherapy – 4 weeks
• Combination therapy – 4 weeks

<u>Intravenous:</u>
≥34/40 gestation - 1.5mg/kg four times a day
<34/40 gestation - 1.5mg/kg twice a day, change to four times a day at 34/40

If switching from IV to oral dosing, use gestational age at birth to decide appropriate dose from the oral dose table.</td><td>Anaemia, neutropenia

Dose banding table if ≥34/40 gestation at birth and >2kg:
<table>
<tr><th rowspan="2">Weight range (kg)</th><th>Oral dose (equivalent to 4mg/kg)</th><th>Volume to be given orally</th></tr>
<tr><th>Twice a day</th><th>Twice a day</th></tr>
<tr><td>2.01 - 2.12</td><td>8.5mg</td><td>0.85ml</td></tr>
<tr><td>2.13 - 2.25</td><td>9mg</td><td>0.9ml</td></tr>
<tr><td>2.26 - 2.37</td><td>9.5mg</td><td>0.95ml</td></tr>
<tr><td>2.38 - 2.50</td><td>10mg</td><td>1ml</td></tr>
<tr><td>2.51 - 2.75</td><td>11mg</td><td>1.1ml</td></tr>
<tr><td>2.76 - 3.00</td><td>12mg</td><td>1.2ml</td></tr>
<tr><td>3.01 - 3.25</td><td>13mg</td><td>1.3ml</td></tr>
<tr><td>3.26 - 3.50</td><td>14mg</td><td>1.4ml</td></tr>
<tr><td>3.51 - 3.75</td><td>15mg</td><td>1.5ml</td></tr>
<tr><td>3.76 - 4.00</td><td>16mg</td><td>1.6ml</td></tr>
<tr><td>4.01 - 4.25</td><td>17mg</td><td>1.7ml</td></tr>
<tr><td>4.26 - 4.50</td><td>18mg</td><td>1.8ml</td></tr>
<tr><td>4.51 - 4.75</td><td>19mg</td><td>1.9ml</td></tr>
<tr><td>4.76 - 5.00</td><td>20mg</td><td>2ml</td></tr>
<tr><td colspan="3">All doses from this table to be prescribed <u>twice a day</u></td></tr>
</table></td></tr>
<tr><td>Lamivudine (3TC) (Epivir®) Liquid 10mg/ml</td><td><u>Oral:</u> usually as part of combination therapy
2mg/kg twice a day – round dose <u>up</u> to nearest 0.5mg to assist administration</td><td>Anaemia, neutropenia
(much less common than with zidovudine)</td></tr>
<tr><td>Abacavir (ABC) (Ziagen®) Liquid 20mg/ml</td><td><u>Oral:</u> usually as part of combination therapy
2mg/kg twice a day– round dose <u>up</u> to nearest 1mg to assist administration</td><td>Hypersensitivity reactions have not been noted in neonates</td></tr>
<tr><td>Tenofovir (TD)
245mg tenofovir disoproxil tablet</td><td><u>Oral:</u> usually as part of combination therapy
All doses based on tenofovir disoproxil salt (TD)

(*245mg TD tablet dissolved in 24.5ml water gives 10mg/ml)
4.9mg/kg (0.49ml/kg*) OD - (round dose <u>up</u> to the nearest - 0.5mg
(<10mg) or 1mg (≥10mg) - 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>
<tr><td>Nevirapine (NVP) (Viramune®)

Liquid 10mg/ml</td><td><u>Oral:</u> usually as part of combination therapy
2mg/kg once a day for 1 week, then 4mg/kg once a day for 1 week
- round doses <u>up</u> to the nearest 0.5mg to assist administration
If mother has already received >3 days of nevirapine:
4mg/kg once a day – (round doses <u>up</u> to the nearest 0.5mg)</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®) 100mg sachets for oral suspension (20mg/ml)</td><td><u>Oral:</u> usually as part of combination therapy in full term neonates ≥37 weeks
1.5 mg/kg once a day from birth to day 7, then 3 mg/kg twice a day until 4 weeks of age - round doses <u>up</u> to the nearest 1mg to assist administration. See dose banding:
<table>
<tr><th>Body weight (kg)</th><th>Dose (mg)</th></tr>
<tr><td colspan="2">Birth to 1 week of life – once a day dosing</td></tr>
<tr><td>2 to <3kg</td><td>4mg once a day</td></tr>
<tr><td>3 to <4kg</td><td>5mg once a day</td></tr>
<tr><td>4 to <5kg</td><td>7mg once a day</td></tr>
<tr><td colspan="2">1 to 4 weeks of life – twice a day dosing</td></tr>
<tr><td>2 to <3kg</td><td>8mg twice a day</td></tr>
<tr><td>3 to <4kg</td><td>10mg twice a day</td></tr>
<tr><td>4 to <5kg</td><td>15mg twice a day</td></tr>
</table></td><td>Rash and liver dysfunction: monitor liver function tests at 5- 7 days of age

Pharmacokinetic data for term neonates ≥37 weeks only</td></tr>
<tr><td colspan="3">PI - Protease inhibitor</td></tr>
</table>

<table>
<tr>
<td>Lopinavir/Ritonavir (Kaletra®)
Liquid:
5ml = (Lopinavir 400mg + ritonavir 100mg)</td>
<td><u>Oral:</u> usually as part of combination therapy
300mg/m^2 (of lopinavir) twice a day – see dose banding table:

<table>
<tr><th>Weight Range (kg)</th><th>Surface Area Range (m2)</th><th>Kaletra Volume TWICE a Day</th></tr>
<tr><td>1-1.5</td><td>0.1- 0.13</td><td>0.5ml</td></tr>
<tr><td>1.51 – 2.0</td><td>0.14 - 0.16</td><td>0.6ml</td></tr>
<tr><td>2.01-2.5</td><td>0.17 - 0.19</td><td>0.75ml</td></tr>
<tr><td>2.51- 3.0</td><td>0.20 - 0.21</td><td>0.8ml</td></tr>
<tr><td>3.01- 3.5</td><td>0.22 - 0.24</td><td>0.9ml</td></tr>
<tr><td>3.51-4.0</td><td>0.25 - 0.26</td><td>1.0ml</td></tr>
<tr><td>4.01-4.5</td><td>0.27 - 0.28</td><td>1.1ml</td></tr>
<tr><td>4.5 - 5</td><td>0.29 - 0.30</td><td>1.2ml</td></tr>
<tr><td colspan="3">All doses from this table to be prescribed TWICE a day</td></tr>
</table></td>
<td>Severe adrenal dysfunction, electrolyte inbalance 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">PCP Prophylaxis</td></tr>
<tr>
<td>Co-trimoxazole (Septrin®)
240mg in 5ml liquid</td>
<td colspan="2"><u>Oral:</u>
<u>≥ 2kg:</u> 120mg once a day on 3 days per week only
<u>< 2kg:</u> 60mg once a day on 3 days per week only</td>
<td>Only for confirmed HIV infected infants, start at 4 weeks of age. May rarely cause rash and bone marrow suppression.</td>
</tr>
</table>

Appendix 5: Neonatal Follow up

At 6 weeks: repeat HIV DNA PCR, FBC, U&E, and LFT
At 6- 8 weeks: Clinic follow up with Paediatric HIV lead consultant
At 12 weeks: repeat HIV DNA PCR, FBC, U&E, and LFT
18 months: Do blood test for HIV antibody test

Mothers are to be informed of all blood results by the Paediatric team. GPs to be informed with mothers' consent.

Interpretation of baby's HIV results:

DNA PCR positive x1 suggests HIV infection. Confirm with viral load, continue Co-Trimoxazole, will require antiretroviral therapy

DNA PCR negative x2 beyond 6 weeks age AND off antiretroviral therapy and at least one after 3 months of age means baby is uninfected. Baby to have HIV antibody test at 18 months of age.

Appendix 6: Side effects of ARVs

- Nausea and vomiting after initiation of antiretroviral therapy may be managed conservatively or with use of anti-emetics.
- Bilirubin should be carefully monitored due to the risk of maternal hyperbilirubinaemia. Abnormalities in liver function tests can be due to initiation of ARVs or other factors like obstetric cholestasis, pre-eclampsia, HELLP syndrome and fatty liver. Serum bile acids and other investigations for liver disease may be required.
- Consider Lactic Acidosis if any woman presents with vomiting, malaise, oedema, abdominal pain and raised transaminases.
- Proteinuria – consider renal toxicity due to ARVs (e.g. Fanconi`s syndrome, if accompanied by glycosuria) or pre-eclampsia (check blood pressure) or urinary tract infection.
- Glycosuria – consider Fanconi`s Syndrome due to ARVs or gestational diabetes.
- Pre-term birth – there is a possible association with ARVs