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1. Foreward

This guidance aims to support health care staff to provide the optimum care for HIV positive women during pregnancy and delivery within Northern Ireland. The guidelines are in keeping with:

1. British HIV Association (BHIVA) Management of HIV infection in pregnant women

2. Royal College of Obstetricians and Gynaecologists, Green-top Guideline No.39: Management of HIV in Pregnancy

3. The Children’s HIV Association (CHIVA) Standards of Care
   www.chiva.org.uk/professionals/health/guidelines/guidelines/standards.html#Standards


The guidelines will be reviewed in January 2016 or sooner if new evidence changes practice. The HIV lead obstetrician; lead Genito Urinary Medicine (GUM) physician for HIV positive pregnant women and lead consultant neonatologist will be responsible for informing the guidelines’ authors of changes in practice.

2. Background

All pregnant women in Northern Ireland should be offered and recommended a screening test for HIV at their booking visit or at the earliest available opportunity if presenting later in pregnancy. Antenatal screening for HIV plays a very important role in identifying HIV positive pregnant women. Early identification of HIV allows for appropriate management and treatment of the mother which can significantly reduce the risk of mother to child transmission (MTCT) of HIV to <1%.
3. Contact telephone numbers for the regional multidisciplinary team at the Royal Group of Hospitals, Belfast Health and Social Care Trust

Dr Priscilla Devaseelan Consultant Obstetrician or On-Call Labour Ward Consultant 028 90632003
HIV Consultant in Genito-Urinary Medicine or On-Call Genito-Urinary Medicine Consultant 028 90240503
Department of Genito-Urinary Medicine (9am-5pm) 028 90634050
GUM Health Advisor 028 90328222
Clinical Lead Nurse, Genito-Urinary Medicine/HIV 028 90634050
Antenatal Screening Coordinator 028 90634847
HIV Pharmacist or Local Trust on call Pharmacist 028 90635443
Dr Richard Tubman, Consultant Neonatologist or On-Call Neonatal Registrar 028 90632441
Dr Sharon Christie, Paediatric Consultant or On-call Infectious Diseases Paediatric Consultant 028 90240503
4. Management of HIV positive pregnant women

Good communication and liaison between members of the multidisciplinary team, the mother and local maternity services (if involved in providing care) is key in ensuring the best possible outcome for the mother and her baby.

- The aim of treatment is to have complete HIV virological suppression at delivery. If this is achieved, and in many cases it is, then the woman’s management during her labour and delivery should follow the same guidelines as for the uninfected woman.

- Women with a viral load (VL) <70 IU/ml (this is the equivalent of <40 HIV RNA copies/ml) are considered as having a complete HIV suppression.

4.1 The role of Antenatal Screening

All women should be offered a HIV screening test early in every pregnancy or at the earliest opportunity if presenting late in pregnancy, in labour or newly delivered as per the National Screening Committee’s Infectious Diseases in Pregnancy Screening Programme: Standards and Laboratory Handbook (DHSSPS: HSS (MD) 43/2010).

Women presenting in labour or requiring delivery without a HIV test result should be offered an urgent HIV test at the first available opportunity and a positive result acted upon immediately with initiation of interventions.

4.2 Newly diagnosed HIV in Pregnant Women

- All newly diagnosed HIV positive pregnant women should be informed of her result in person by an appropriate professional of the obstetric screening team.

- If time permits, she should be advised that she should have her care transferred to the regional multidisciplinary team (RMDT) for the ongoing management of her pregnancy and HIV disease. However, interventions should not be delayed especially in patients whose labour/delivery is impending.

- The RMDT is based at the Royal Group of Hospitals in Belfast Health and Social Care Trust, and includes health professionals from Genito Urinary Medicine (GUM), obstetrics, neonatology, paediatric infectious diseases, midwifery, specialist pharmacy, HIV counselling, and HIV nursing.

For women requesting obstetric care in her local Unit any decision must be made in consultation with the RMDT. All care should be provided in close consultation with the RMDT.

4.3 Referral

Most referrals to the RMDT will either be women who are identified as HIV positive through the antenatal screening programme or women known to be HIV positive who become pregnant. The latter group will, most probably, be already known to the GUM team.

- Routine referrals can be made initially by telephone (Section 3) and followed up in writing to the Royal Jubilee Maternity Hospital (RJMH) obstetric consultant and Royal Group Hospitals (RGH) GUM consultant responsible for HIV positive pregnant women.
● **Urgent referrals** are women diagnosed late in the antenatal period (≥20^{+0} weeks gestation); diagnosed in labour; or immediately post-partum; or patients who develop complications requiring urgent or immediate advice on management. The relevant team members should be contacted via the contact numbers in Section 3.

● **Auditable target:** All routine referrals of newly diagnosed HIV positive women identified during pregnancy should be referred and seen by GUM team by 20 weeks gestation (Target: >97%).

### 4.4. Issues for RMDT to discuss with patient

- The RMDT will discuss the following with the woman:
  - HIV effect on pregnancy
  - Effect of pregnancy on HIV
  - Prevention of transmission to the child
  - Confidentiality and informing key health professionals
  - Partner notification and testing of partner and other children
  - Drug therapy
  - Family/social support
  - Obstetric/antenatal care
  - Mode of delivery
  - Infant feeding including recommendation of avoidance of breast feeding
  - Postnatal care and assessing status of child

- The woman should be encouraged to allow disclosure of HIV status and care plan between all health care professionals involved in her care, including GP. The disadvantage in potential medical error due to insufficiently shared information, risking both mother and baby, should be highlighted. However, confidentiality is of paramount importance and the woman should be reassured that her wishes will be respected and that her consent will be obtained prior to notification of any health care professionals.

- Once the patient has been seen by GUM service, the GUM team will assume the responsibility of partner notification and testing of other children (if relevant).

### 4.5. HIV Management

- The best clinical practice should be based on most up to date national guideline produced by BHIVA.
  

- **The most important factor that predicts the risk of mother to child transmission is the level of HIV virological suppression at delivery.**
  
  - For the majority of cases presenting early, complete suppression <70 IU/ml (this is the equivalent of <40 HIV RNA copies/ml) should be achievable by delivery. This depends greatly on the woman’s ability to adhere to her antiretroviral (ARV) drug regime. Support in coping with her situation, addressing drug tolerance, side effects, patient education, and simple aids like a pill box, have all been shown to improve adherence.
  
  - For the majority of cases who achieved complete suppression <70 IU/ml (this is the equivalent of <40 HIV RNA copies/ml) without other complicating factors – the management of the woman through her labour and delivery should follow the same guidelines as for the uninfected woman.
4.6. Roles and Responsibilities in Antenatal Care

4.6.1. GUM Services

- The GUM service will advise on the management of HIV for the mother.

- GUM is responsible for the following

  o In early cases – aim to have initial consultation by 20 weeks gestation. For late cases (not in labour) – aim to facilitate earliest possible consultation.
  o Baseline clinical assessment of the woman at her initial visit: CD4 count, HIV viral load, HIV resistance testing, HIV Pro-viral DNA; and other baseline investigations that would be performed for non-pregnant new HIV diagnosis. Consideration should also be given to screening for chicken pox immunity.
  o Completion of STI check – this should include chlamydia/gonorrhoea/Hepatitis C. Syphilis and Hepatitis B should be done if not already performed as part of the antenatal screen. Other infections may be investigated based on clinical indications. A repeat STI check may be performed at later stage of pregnancy if there are ongoing risks.
  o Decision on when and which ARVs to start (if not already on)
    - Woman with indication to initiate ARVs for her own health – ARVs are usually initiated as soon as possible, normally these ARVs must be continued post delivery
    - Woman without indication for ARVs for herself but ARVs are needed to reduce the risk of MTCT – ARVs are generally initiated from approximately 22 weeks gestation. Normally in this situation, ARVs may be discontinued post delivery.
  o Performing the monitoring investigation related to ARVs (including FBP, U+E, LFT) and virological responses: every 3-4 weeks following ARV initiation until complete suppression has been achieved. After this, these women will usually be monitored at the frequency of 6-8 week intervals. A viral load is usually done around 36-37 weeks gestation to facilitate obstetric decision on mode of delivery.
  o Consideration for empirical herpes simplex virus (HSV) suppression– frequently the GUM team may initiate acyclovir 400mg BD from 28-32 weeks gestation. The aim is to reduce HSV shedding. In most case, the acyclovir may be discontinued postpartum.
  o For all women who discontinued ARVs postpartum, the GUM clinician would review the woman around 3-4 weeks postpartum – including assessment of viral load for potential resistance testing.

- The GUM service provide a summary regarding the woman’s HIV proposed management early in pregnancy and covers:
  o The proposed maternal HIV management
  o HIV viral load
  o Indicate if ARVs (and acyclovir in selected case) can be discontinued postpartum
  o Results from the STI screen.

- The mother’s care plan (Appendix 1) should be discussed with the woman and copies kept in her GUM and maternity hand held records. Decision for delivery is usually made at the 36 week appointment. The GUM service should ensure there is a mechanism for communicating updates of management, especially when there are any changes, to all the health professionals involved in her care.

- It is important for GUM service to recognise that there are potential overlapping presentations between adverse side effects of ARVs and complications of pregnancy, for examples pre-
eclampsia, cholestasis and other signs of liver dysfunction. Early liaison between obstetric and GUM consultants is important to avoid misdiagnosis.

- During the care of these women, clinicians outside the GUM service may need to prescribe other medications – it is the responsibility of the prescriber to ensure they have considered potential drug-drug interactions with antiretroviral drugs. [http://www.hiv-druginteractions.org/](http://www.hiv-druginteractions.org/) is a useful website that contains up to date information. Help on such issues may also be sought from the HIV specialist pharmacist based in RGH GUM service.

- This simplified overview cannot be applied to all situations and each maternal care plan (Appendix 1) is individually developed and can depend on a variety of clinical factors. Management should follow the most recent advice and guidelines from the British HIV Association (BHIVA). [http://www.bhiva.org/documents/Guidelines/Treatment/2012/120430PregnancyGuidelines.pdf](http://www.bhiva.org/documents/Guidelines/Treatment/2012/120430PregnancyGuidelines.pdf)

4.6.2 The Obstetric Team

- The obstetric team will advise on the management of pregnancy for the mother, including regular reassessment of anticipated mode of delivery.

- The obstetric team is responsible for the following
  
  o Recognising that for the majority, if the woman’s viral load become fully suppressed i.e. <70 IU/ml (this is the equivalent of <40 HIV RNA copies/ml) by delivery, the obstetric care should follow the same guidelines as for the uninfected community.
  
  o Prompt referral to GUM. This is because:
    - GUM clinicians should see patient by 20 weeks gestation
    - A minimum of 2 weeks is required for the baseline assessment results to become available, to permit optimal selection of ARV treatment
    - Ideally ARV treatment should be initiated by 22 weeks gestation.
  
  o Liaison with the consultant neonatologist. This should include arranging an appointment for the woman with the consultant neonatologist prior to delivery to discuss child issues (including the avoidance of breast feeding), concerns, treatment and testing of the infant.
  
  o Discuss with the woman, the proposed obstetric management including issues such as antenatal monitoring of mother and baby, obstetric interventions in labour, mode of delivery and the avoidance of breastfeeding. Consider iron supplements in the second and third trimester. Iron preparations such as ferrous sulphate should be given rather than combinations containing both iron and folate such as pregaday.
  
  o Have a basic understanding of the virological response to ARV treatment:
    - It takes time for any antiretroviral regime to work – a typical expectation might be approximately 1.5 log reduction in viral load over every 4 weeks – GUM will perform these tests.
    - For the majority of women, complete virological suppression should be anticipated to be achievable by 12-14 weeks after initiation of ARV treatment. For those initiating therapy around 22 weeks gestation, complete suppression should be achievable by 34-36 weeks gestation.
  
  o Basic understanding of anticipated virological response will aid the anticipation of any deviation and help pre-plan the peri-partum requirement and the mode of delivery. This includes ensuring the required antiretroviral drugs for peri-partum use is held in stock on the labour ward.
Review the anticipated mode of delivery - this should be discussed with the woman and recorded in the notes. The obstetric service should ensure there is a mechanism for communicating the updates, especially when there are any changes, to all the health professionals involved in her care. This includes consideration for regular communication to GUM service about the obstetric care plan – especially if there are any obstetric factors that may influence the risk of MTCT and affect the individualised care plan outlined by the GUM service.

- In women where complete virological suppression is unlikely, the individualised plan need to be jointly decided with GUM, with reference to best practice based on BHIVA guidelines.

- In some cases ARV treatment is stopped post delivery – but for some women it is continued. Instructions on the continuation of ARV treatment are normally decided in advance by GUM and documented in the care plan. Anti-retroviral drugs should not be stopped if this instruction is unclear as incorrectly discontinued drug regime may risk the development of drug resistant virus which could be harmful to the woman.

- This simplified overview cannot be applied to all situations and every care plan will need to be developed on a case by case basis and will depend on a variety of clinical factors. Management should follow the most recent advice and guidelines from the British HIV Association (BHIVA).

- It is important for the obstetric team to recognise that there can be potential overlapping presentations between adverse side effects of ARV treatment and complications of pregnancy, for examples pre-eclampsia, cholestasis and other signs of liver dysfunction. Early liaison between obstetric and GUM consultants is important to avoid misdiagnosis.

- During the care of these women, when prescribing any medications the prescriber should ensure they have considered potential drug-drug interactions with antiretroviral drugs. [http://www.hiv-druginteractions.org/](http://www.hiv-druginteractions.org/) is a useful website that contains up to date information. Help on such issues may also be sought from the HIV specialist pharmacist based in RGH GUM service.

- All Units hold an emergency HIV drug pack containing the drugs that a woman and her infant may require (see unplanned admission treatment scenarios below). A protocol for the preparation and use of zidovudine is also included.

### 4.7. Delivery

- All women should strongly be advised by the diagnosing team and RMDT or the local obstetric unit about the importance of revealing their HIV status to maternity staff providing care to ensure prompt and optimum management of the pregnancy, labour and delivery.

- Most women will be managed by RMDT via RJMH in Belfast – however if an unplanned admission occurs outside RJMH as an emergency, it is not always appropriate to immediately transfer the woman – use section 4.6. to decide if intervention is immediately necessary or if there is time for arranging transfer.

- Although communication with the RMDT members is essential there should not be a delay in commencing treatment whilst members of the RMDT are contacted.
• In the event of any unplanned admission the following RMDT members should be informed:
  o Obstetrician at time of admission
  o GUM consultant at time of admission
  o Neonatologist (if in labour or delivered)
  o Antenatal screening coordinator (RJMH) ASAP during normal working hours
  o Clinical lead nurse GUM/HIV ASAP during normal working hours

4.7.1 Spontaneous labour / Spontaneous ROM < 34 weeks

• Intramuscular steroids should be administered in accordance with national guidelines
• Virological control should be optimized
• When PPROM occurs at <34 weeks
  o The RMDT should be consulted about the choice of antibiotics and timing of delivery

4.7.2 Spontaneous labour / Spontaneous ROM > 34 weeks

• There are 2 principal scenarios:
  o Women who are on combined ARV treatment - follow Pathway 1
  o Women not on ARV treatment presenting in labour or on mono ARV – follow Pathway 2

Pathway 1 - Women on ARV treatment

Look up most recent HIV viral load (within 4 weeks)
  - Result may be in A/N proforma or accessed via Belfast Trust LabCentre #

If VL < 70 IU/ml*
  - Assess for other factors that may increase risk of MTCT e.g. amnionitis, concurrent STIs, patient non-adherent to ARV (post VL date)

No other risk
  - Manage delivery as per non-infected woman
  - If ROM > 34 weeks gestation, delivery should be expedited with augmentation of labour

If VL > 70 IU/ml* or if no VL within 4 weeks
  - Discuss with HIV consultant in GUM and obstetric consultant
  - Assess trend of serial VL and trajectory / patient adherence
  - Consider following Pathway 2

Other factors
  - Discuss with HIV consultant in GUM and obstetric consultant
  - Consider following Pathway 2

* 70 IU/ml equates to approx 40 HIV RNA copies/ml
# The SP number for checking laboratory viral load results can be found at the top of the Mother’s care Plan.
Pathway 2 – Women not on ARV or on mono therapy or if viral load >70* IU/ml

DO NOT delay delivery, in ORDER of priority
- Aim to deliver < 6 hours from ROM by caesarean section TOP PRIORITY
- AVOID vaginal delivery where at all possible
- Prescribe and administer ARV drugs STAT as per situations below (the emergency drug pack is held on delivery suite)
  If mother is not on ARV and has an unknown viral load the primary aim in giving the mother the drugs is to load up the baby to a reasonable prophylactic level. The time required for this must be balanced against risk of infection when there is ROM. The base risk of infection increases by 2% every hour after the first four hours of ROM.
- If the woman is only diagnosed in labour – send 2 X clotted bloods for confirmation of HIV status to Regional Virology Lab using routine virology form.
- If vaginal delivery is unavoidable, avoid invasive testing that may encourage maternal-fetal blood exposure (e.g. fetal scalp monitoring, fetal blood sampling). If instrumental delivery is indicated, forceps is preferable to ventouse. Contact obstetric HIV consultant, GUM HIV consultant and neonatal team ASAP.
- Transfer to RJMH only with regional team approval and if time permits.

For 4 most probable situations for drugs – see below

**Situation 1:** Woman not on ARV treatment, labour at term
- Nevirapine 200mg stat
- Prescribe (and give first dose ASAP)
  - Raltegravir 400mg BD
  - Lamivudine 150mg BD
  - DO NOT STOP POST PARTUM
- IV zidovudine throughout labour and delivery

**Situation 2:** Woman not on ARV treatment and pre-term labour
- Nevirapine 200mg stat (+ Tenofovir 490mg stat - only available RJMH)
- Prescribe (and give first dose ASAP)
  - Raltegravir 400mg BD
  - Lamivudine 150mg BD
  - DO NOT STOP POST PARTUM
- IV zidovudine throughout labour and delivery

**Situation 3:** Woman on combined ARV treatment
- Nevirapine 200mg stat
- Continue ARV orally – take Lamivudine150mg instead of Combivir® (Zidovudine 300mg/Lamivudine 150mg) while IV Zidovudine is running
- IV zidovudine throughout labour and delivery
- CHECK CAREPLAN – only stop ARV post partum if clearly documented

**Situation 4:** Woman on mono ARV treatment
- Nevirapine 200mg stat
- IV zidovudine throughout labour and delivery
- CHECK CAREPLAN – only stop ARV post partum if clearly documented

* 70 IU/ml equates to approx 40 HIV RNA copies/ml
\(^*\) (Note: Combivir® (Zidovudine 300mg/Lamivudine 150mg) cannot be given while IV Zidovudine is running as it will result in a double dose of zidovudine being given. Therefore Lamivudine 150mg only should be given while IV zidovudine is being administered. Once IV Zidovudine has stopped Combivir® (Zidovudine 300mg/Lamivudine 150mg) can be continued).
Each maternity unit should hold an emergency pack of HIV drugs for a woman and her infant to cover instances of unplanned admission and delivery. The drug pack includes a protocol for the preparation and use of zidovudine.

4.7.3 Planned delivery

- All known HIV positive women should have an individualised, regularly updated, plan of care summarising the agreed obstetric/GUM management for each woman, including the drug regime and recommended mode of delivery. A copy of this plan of care should be held by the pregnant woman and the consultant neonatologist. It should also be included in her maternity and GUM notes. Women are encouraged to carry their maternity hand held records to improve communication and continuity of care.

4.7.4 Other considerations

- All Trusts have a policy on infection control procedures and staff should adhere to their Trust policy when providing care for HIV positive women. Universal infection control measures, properly applied, provide adequate protection for staff.

- All delivery suites should ensure that they are equipped with appropriate blunt needles, drapes, gloves, visors, etc. for operative procedures.

4.8 Post-natal Management

- The on-call neonatal registrar should be informed immediately after delivery.

- The neonatal registrar should commence, within 4 hours of birth, the infant’s antiretroviral drug treatment as indicated in the woman’s maternity hand held record. If this is unavailable or unclear, advice from the on-call consultant neonatologist should be sought.

- For the preparation and dose of the medication, please refer to the Guidelines for the Management of the HIV Exposed Infant (at the end of these guidelines).

- Take the baby’s bloods according to the Guidelines for the Management of the HIV Exposed Infant. A 5 ml sample of maternal whole blood in an EDTA bottle must also be sent along with the baby’s sample (appendix 3).

- The mother’s HIV positive status alone is not a reason for the baby to receive care in the Special Care Baby Unit. The baby should, whenever possible, stay with mother.

- HIV positive women should be strongly advised against breastfeeding. In the absence of other interventions breastfeeding doubles the risk of mother-to-child HIV transmission.
Guidelines for the Management
of the
HIV Exposed Infant

Reviewed: February 2013
Next review: February 2016
Guidelines for the management of the HIV exposed infant

Prior consultation must be made with the HIV team. The mother’s individual care plan (Appendix 1) should be drawn up well in advance of delivery. The mother should be given a copy of this to put in her maternity hand held notes. It is important to be aware of current maternal anti-retroviral drug status and most recent viral load, as these will affect the choice of drug(s) to be used in the neonate. Good communication and team working are vital.

5.1 Reducing the risk of perinatal infection

- The mother should have oral antiretroviral therapy (ART), plus intravenous zidovudine, if clinically indicated, to cover the period of labour and delivery. The treatment will have been organised by the HIV specialist and will be documented in the mother’s care plan.

- Intrapartum intravenous zidovudine infusion is recommended in the following circumstances:
  - For women with a viral load of >10,000 HIV RNA copies/ml (>17,400 IU/ml) plasma who present in labour, or with ruptured membranes or who are admitted for planned C/S
  - 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 PLCS intravenous zidovudine can be considered. Continued oral dosing is a reasonable alternative.

- Zidovudine (ZDV) monotherapy is recommended if maternal viral load is less than the lower limit of detection at 36 weeks’ gestation or thereafter prior to delivery. The baby should be prescribed zidovudine syrup beginning as soon as possible after birth and ideally within 4 hours. It should be continued for 4 weeks.

- The dose of ZDV depends on the baby’s weight and gestational age (see Section 5.8 below). In sick infants or those unable to tolerate oral feeds, give IV Zidovudine.

- Three-drug infant therapy is recommended for all circumstances other than the above, where maternal viral load at 36 weeks gestation/delivery is not less than the lower limit of detection. For babies of ART-naïve women the combination of ZDV, Lamivudine (3TC) and Nevirapine (NVP) is used most frequently. For non-naïve women seek specialist advice.

- There are three situations where triple combination ART is advisable.
  - Where the mother is found to be HIV infected only after delivery
  - Unplanned delivery, e.g., prior to starting ART or where maternal HIV details are not available.
  - Persistent maternal viraemia (high viral load) on highly active antiretroviral therapy (HAART).

5.2 Feeding

- All mothers known to be HIV positive, regardless of antiretroviral therapy, and infant post-exposure prophylaxis, should be advised to exclusively formula feed from birth.

[In the very rare instance where a mother who is on effective HAART with a repeatedly undetectable viral load chooses to breast feed, this should not constitute grounds for automatic referral to child protection teams. Maternal HAART should be carefully monitored and continued until one week after all breastfeeding]
Breastfeeding, except during the weaning period, should be exclusive and all breastfeeding, including the weaning period, should have been completed by the end of 6 months. Prolonged infant prophylaxis during the breastfeeding period, as opposed to maternal HAART, is not recommended. Intensive support and monitoring of the mother and infant are recommended during any breastfeeding period, including monthly measurement of maternal HIV plasma viral load, and monthly testing of the infant for HIV by PCR for HIV DNA/RNA (viral load).

5.3 General care

- The baby should be cleaned before leaving labour ward to remove any maternal blood.
- HIV positive status alone is not a reason for admission to the neonatal unit. The baby should whenever possible stay with his/her mother.
- The maternal records should be checked for documentation of other infections that might affect the baby, e.g., hepatitis B and C, syphilis, tuberculosis, cytomegalovirus, toxoplasmosis, chlamydia, gonorrhoea, and herpes simplex. Remember that lack of documentation does not exclude any of these.
- Note should be made of any other significant maternal issues, e.g., need for interpreter services, substance abuse, psychosocial factors.
- Staff should adhere to universal precautions against infection. Consult the most up to date local policies.
- Most HIV-exposed babies are of normal birth weight and do not have any abnormal clinical findings - hepatosplenomegaly, lymphadenopathy, microcephaly etc. should prompt a search for other causes (e.g., other infections).
- Clinical status, growth and development should be monitored carefully at the baby clinic (Dr Tubman’s Tuesday clinic).

5.4 Laboratory Diagnosis of HIV infection in the infant

Send blood samples to the local virology laboratory using the specific “Congenital HIV Transmission Follow Up” forms (appendices 2 and 3). Do not use a routine virology request form. Use Category 3 green stickers on all samples and forms.

The following laboratory evaluation schedule should be followed:

<table>
<thead>
<tr>
<th>Age</th>
<th>Day One(^1)</th>
<th>2 weeks(^3)</th>
<th>6 weeks</th>
<th>3 months</th>
<th>12 months</th>
<th>18 months</th>
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<tbody>
<tr>
<td>HIV tests(^2)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>FBC(^3)</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U+E, Creat., LFTs(^3)</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Notes

\(^1\) Do not use cord blood for newborn sample and use infant lab form (appendix 2).
A 5 ml sample of maternal whole blood in an EDTA bottle must also be sent along with the baby’s sample (appendix 3). In view of the genomic diversity of HIV where infant diagnosis will rely on HIV DNA amplification, a maternal sample should always be obtained for HIV DNA amplification with, or prior to, the first infant sample to confirm that the primers used detect the maternal virus. Remember to label all bottles and forms correctly. Ensure tops are secured. Avoid any blood staining of the bottle label.

2 HIV screening tests: 2 ml whole blood in EDTA bottle. Mix gently. (Plasma is used for HIV1 and HIV2 antibody and HIV RNA detection. White blood cells from the cellular fraction are used for HIV DNA PCR testing).

Sexually Transmitted and Blood Borne Viruses Laboratory, Health Protection Agency, 61 Colindale Avenue, London NW9 5HT - Tel. 020 8200 4400 ext. 3204

3 Initially to monitor anti-retroviral treatment. May need further FBP samples, Full blood count and platelets, U+E, glucose, creatinine, LFT’s.

Triglycerides, amylase, lactate or pH may be needed particularly when newer or combination therapy is used, or if the baby is symptomatic whilst on treatment, but not routinely.

CD4+ lymphocyte count and percentage, immunoglobulins or other tests are not indicated routinely unless PCR is positive or there are signs of infection.

Diagnosis

HIV positive antibody testing in an infant aged less than 18 months indicates maternal infection but does not diagnose infection in the infant. If PCR continues to remain negative at 3 months there is a > 95% chance of being uninfected. Testing for loss of maternal HIV antibody remains important as rarely, late postnatal infection may occur even when all early HIV viral genome diagnostic tests were negative (French Perinatal cohort: 5/4539 cases). This may be due to covert breastfeeding, premastication of infant food or unknown interfamilial exposure.

An HIV exposed infant is considered uninfected when there are no physical signs to suggest infection, immunological tests are normal, virological tests of infection are negative, and after 12 months from birth two or more HIV antibody tests are negative.

NB: If PCR is positive, repeat HIV tests immediately to confirm infection. If the infant is shown to be infected (2 positive PCR) he/she should be referred promptly by phone to Dr Sharon Christie or Dr Paul Jackson, RBHSC.

In addition, both the mother and child should have urgent resistance testing performed.

5.5 Prophylaxis for Pneumocystis jirovecii pneumonia (“PCP”)

- There is no need to give routine PCP prophylaxis if maternal viral load is below the lower limit of detection at delivery.

- PCP prophylaxis should be prescribed to infants born to mothers who received no intrapartum prophylaxis, e.g. following unbooked or unexpected preterm delivery; or where maternal viral load at 36 weeks or at delivery is > 1,000 RNA copies/ml (>1,740 IU/ml) despite ART or where the baby has a positive HIV RNA/DNA test.
• Commence prophylaxis at 4 weeks of life, when anti-retroviral treatment is stopped.

• Treat with co-trimoxazole, once per day orally, 3 times per week (on Monday, Wednesday and Friday). See section 7 below for dose.

• Prophylaxis beyond 4-6 months should be given to infected infants or those whose infection status is uncertain. Consult a specialist in paediatric HIV/AIDS.

5.6 Immunisations

• Consult Department of Health immunisation handbook if in doubt.

• Give standard immunisations (DTPer, Hib, meningitis C, Polio) at usual times.

• Commence Hepatitis B immunisation in all infants according to standard protocol (See also Section 6 below for babies of HBV positive mothers).

• BCG administration is not recommended until the infant has a negative 3-month PCR test. If tuberculosis screening indicates high risk – seek specialist advice.

• Please complete the Unscheduled Immunisation Record form and send copies to the Child Health System and the Health Visitor.

5.7 Hepatitis B/C and HIV co-infection

• Infants born to HBsAg positive women should receive active immunisation at birth, 1 month, 2 months and 12 months of life. Babies born to mothers who are high risk should receive HBIG at birth as well as active immunisation, according to the Table below

<table>
<thead>
<tr>
<th>Hepatitis B status of mother</th>
<th>Baby should receive:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hepatitis B vaccine</td>
</tr>
<tr>
<td>Mother is HBsAg positive and HBeAg positive</td>
<td>Yes</td>
</tr>
<tr>
<td>Mother is HBsAg positive, HBeAg negative and anti-HBe negative</td>
<td>Yes</td>
</tr>
<tr>
<td>Mother is HBsAg positive, where e-markers have not been determined</td>
<td>Yes</td>
</tr>
<tr>
<td>Mother had acute Hepatitis B during pregnancy</td>
<td>Yes</td>
</tr>
<tr>
<td>A woman who is HBsAg seropositive and known to have an HBV DNA level equal to or above 1 x 10^6 ius/ml in an antenatal sample*</td>
<td>Yes</td>
</tr>
<tr>
<td>Mother is HBsAg seropositive and infant is born weighing 1500g or less</td>
<td>Yes</td>
</tr>
<tr>
<td>Mother is HBsAg positive and anti-HBe positive</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Department of Health Green Book

• HBIG should preferably be given within 24 hours of delivery and should be ordered well in advance of the birth. HBIG can be given simultaneously with vaccine but in a different site.

• It is important that premature babies receive the full paediatric dose of hepatitis B vaccine on schedule. For low birth weight babies born to mothers infected with hepatitis B, HBIG should
be given, in addition to vaccine, to babies with a birth weight of 1500g or less, regardless of the e antigen status of the mother.

- Infants of Hepatitis B positive mothers should be screened at 15-18 months for HBsAg (to exclude infection) and HBsAb (to confirm response to vaccination). **These must be explicitly requested** for on the virology request form (i.e., checking status of an immunised baby).

- Testing for HCV PCR is recommended for all infants born to dually infected (HIV/HCV) mothers. Antibody testing is unreliable until the infant is 15-18 months old. Repeat PCR testing for HCV RNA should be performed during the first year of life.

### 5.8 Doses of drugs commonly used in infants

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose regimen</th>
<th>Formulation</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zidovudine (ZDV)</td>
<td>Orally</td>
<td>“Retrovir” suspension, 50 mg/5 ml</td>
<td>Check whether single or triple therapy needed. S/E: anaemia, neutropenia, thrombocytopenia, altered liver function, pancreatitis, lactic acidosis. Interactions* phenytoin, stavudine</td>
</tr>
<tr>
<td></td>
<td>&gt; 34 weeks gestation: 4 mg/kg/dose BD for 4 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>30-34 weeks gestation: 2 mg/kg/dose BD x 2 weeks, then 2 mg/kg/dose TID x 2 weeks.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 30 weeks gestation: 2 mg/kg/dose BD x 4 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Intravenous</strong> &gt; 34 weeks gestation: 1.5 mg/kg/dose QID</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>≤ 34 weeks gestation: 1.5 mg/kg/dose BD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lamivudine (3TC)</td>
<td>2 mg/kg/dose orally BD for 4 weeks.</td>
<td>“Epivir” suspension, 10 mg/ml</td>
<td>As part of triple therapy S/E: anaemia, neutropenia, thrombocytopenia, altered liver function Interactions* ganciclovir, co-trimoxazole</td>
</tr>
<tr>
<td>Nevirapine (NVP)</td>
<td>If the mother has not taken NVP: 200mg to mother in labour.</td>
<td>“Viramune” suspension 50 mg/5 ml</td>
<td>As part of triple therapy. S/E: renal or</td>
</tr>
<tr>
<td><strong>Baby</strong></td>
<td>2 mg/kg orally once per day for 1(^{st}) week then 4 mg/kg orally once per day for the 2(^{nd}) week. If the mother has taken NVP for &gt; 3 days before birth: 4 mg/kg orally once per day x 2 weeks.</td>
<td>hepatic impairment, rash. Interactions* cimetidine, macrolides, protease inhibitors, rifampicin. Avoid single dose regime as may encourage resistance</td>
<td></td>
</tr>
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<td></td>
</tr>
</tbody>
</table>

**NB: Stop NVP 2 weeks before stopping other ARTs**

<table>
<thead>
<tr>
<th><strong>Co-Trimoxazole</strong></th>
<th>PCP Prophylaxis: 900 mg/m² orally OD on three days per week (M/W/F). In practice, 4-8 kg weight: 120 mg once daily Mon, Wed, Fri 8-12 kg weight: 240 mg once daily Mon, Wed, Fri</th>
<th>Co-trimoxazole paediatric suspension 240 mg/5 ml (= 40 mg trimethoprim plus 200 mg sulphamethoxazole / 5 ml) S/E: Rash, bone marrow suppression Interactions* anticonvulsants, lamivudine, digoxin</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Aciclovir</strong></th>
<th>Dosage regimens vary, seek specialist advice. If present or past history of maternal HSV, discuss management of infant with GUM/paediatric ID/neonatology specialists</th>
<th>“Zovirax” suspension 200 mg/5 ml Caution in renal or hepatic impairment. Monitor neutrophil count.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Hepatitis B Vaccine</strong></th>
<th>10 mcg</th>
<th>“Engerix B” 10 mcg in 0.5 ml</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Hepatitis B Immunoglobulin</strong></th>
<th>200 IU</th>
<th>See hospital protocol</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>BCG Vaccination</strong></th>
<th>0.05 ml of PPD given intradermally at insertion of deltoid on left upper arm.</th>
<th>See hospital protocols. Ensure good bleb. Assistance to hold baby still is vital.</th>
</tr>
</thead>
</table>

*Antiretroviral drugs interact with many medicines. For further drug information including drug interactions, and information on adverse effects please contact specialist pharmacist.*
6 References

1. British HIV Association (BHIVA) Management of HIV infection in pregnant women

2. Royal College of Obstetricians and Gynaecologists, Green-top Guideline No.39: Management of HIV in Pregnancy

3. The Children’s HIV Association (CHIVA) Standards of Care
   www.chiva.org.uk/professionals/health/guidelines/guidelines/standards.html#Standards

### GLOSSARY

**ART/ARV** Antiretrovirals are drugs used to treat retroviral infections like HIV. The drugs do not kill the virus. However, they slow down the growth of the virus. When the virus is slowed down, so is HIV disease. Antiretroviral drugs are referred to as ARV. ARV therapy is referred to as ART or HAART (Highly Active Antiretroviral Therapy).

**CD4 cells** Also called T cells or CD4+ T cells. These are infection-fighting white blood cells of the immune system. HIV destroys CD4 cells, making it harder for the body to fight infections.

**CD4 count** The number of CD4 cells in a sample of blood. A CD4 count measures how well the immune system is working. CD4 cells may also be measured as a percentage.

**GUM** Genito Urinary Medicine department. HIV care is provided at the GUM department in Royal Group of Hospitals, Belfast Health and Social Care Trust.

**HAART** This stands for highly active antiretroviral therapy and is the name given to aggressive treatment regimens used to suppress HIV viral replication and the progression of HIV disease. The usual HAART regimen combines three or more different drugs.

**HIV** Human Immunodeficiency Virus belongs to a group of viruses called ‘retroviruses’. HIV attacks the immune system and gradually causes damage. This can mean that a person infected with HIV is at risk of developing some serious infections and cancers that a healthy immune system can fight off. HIV is present in blood, genital fluids and breast milk. One way of passing on the infection is from a mother to her baby during pregnancy, birth or through breastfeeding.

**LOG reduction** Log stands for logarithm, which is the exponent of 10. For example, Log 2 represents 10² or 10 x 10 or 100. Log reduction stands for a 10-fold (or one decimal) or 90% reduction in numbers of live virus. Another way to look at it is: 1 Log reduction would reduce the number of virus 90%. This means, for example, that 100 virus would be reduced to 10, or 10 reduced to 1.

- A 1 log reduction means 10 times less amount of virus
- A 2 log reduction means 100 times less amount of virus
- A 3 log reduction means 1000 times less amount of virus
- A 4 log reduction means 10,000 times less amount of virus

**MTCT** Mother-to-child transmission (MTCT) of HIV, also called perinatal or vertical transmission, occurs when HIV is passed from a HIV positive woman to her baby during pregnancy, labour and delivery or breastfeeding. For a HIV positive woman not being treated for HIV, the chance of passing the virus to her child is about 25% during pregnancy, labour and delivery. If she breastfeeds her infant, there is an additional 12% chance of transmission.

**RGH** Royal group of hospitals.
RJMH  Royal Jubilee Maternity Hospital where the RMDT is sited. All HIV positive women are referred to RJMH for care. For women who request care at their local unit this must be discussed and agreed with the RMDT and the local consultants.

RMDT  Regional multidisciplinary team consists of specialist professionals from obstetrics, midwifery, HIV medicine and nursing, neonatology and paediatric infectious diseases within the Royal Group of Hospitals.

Viral load  The amount of HIV RNA in the blood. One of the goals of antiretroviral therapy is to reduce the viral load which reduces the risk of transmitting HIV. The Regional Virus Laboratory uses the Abbott Real Time HIV-1 Viral Load assay which reports results in International Units/ml (IU/ml).

- When the amount of HIV RNA in a person’s blood is too low to be detected this is reported as “HIV-1 RNA not detected.”
- When HIV RNA is detected but at the limit of detection of the assay this is reported as <70 IU/ml (Log value <1.84), this equates to approximately <40 HIV RNA copies/ml.
- 1 IU/ml =0.58 HIV RNA copies/ml, 1 copy =1.74 IU
MOTHER’S CARE PLAN

Name: ___________________________  D.O.B: / / 

RJMH No: _______________________  GUM No SP __________________

**Initial assessment – HIV status**

<table>
<thead>
<tr>
<th>Positive pre-conception</th>
<th></th>
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<tbody>
<tr>
<td>Less than 28 weeks gestation</td>
<td></td>
</tr>
<tr>
<td>28 to 36 weeks gestation</td>
<td></td>
</tr>
<tr>
<td>More than 36 weeks gestation</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 1: GUM TO UPDATE**

<table>
<thead>
<tr>
<th>Baseline</th>
<th>Date</th>
<th>Result</th>
</tr>
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<tbody>
<tr>
<td>Viral load</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hep B status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hep C status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VDRL/TPPA</td>
<td></td>
<td></td>
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<tr>
<td>Pro-viral DNA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measles IgG (EIA)</td>
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<tr>
<td>Varicella Zoster IgG</td>
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<tr>
<td>Toxoplasma IgG</td>
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<tr>
<td>HSV-2 type specific</td>
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<tr>
<td>STI screen</td>
<td></td>
<td>GC</td>
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<td>CT</td>
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<td></td>
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<td>N/A</td>
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**Antiretroviral plan:**

<table>
<thead>
<tr>
<th>Patient already on ART</th>
<th>Regime:</th>
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</thead>
<tbody>
<tr>
<td>Patient not on ART</td>
<td>Need for ART for self indication ☐</td>
</tr>
<tr>
<td></td>
<td>Need ART from 22 weeks for MCT risk reduction ☐</td>
</tr>
<tr>
<td>Anticipated plan for</td>
<td>Continue with ART postpartum ☐</td>
</tr>
<tr>
<td>ART postpartum</td>
<td>Stop ART postpartum ☐</td>
</tr>
</tbody>
</table>

Date of initiation of HAART: _________________  Gestation: _____ weeks

Regime: __________________________________________________________

<table>
<thead>
<tr>
<th>3rd trimester</th>
<th>Date</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>STI screen</td>
<td></td>
<td>GC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N/A ☐</td>
</tr>
<tr>
<td>VDRL/TPPA</td>
<td></td>
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</tbody>
</table>

Appendix 1
<table>
<thead>
<tr>
<th>Date</th>
<th>Gestation</th>
<th>CD4</th>
<th>Viral load*</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

**Additional information:**

**SECTION 2: OBSTETRIC TEAM INPUT**

**EDD ______________**

**Any relevant maternal/fetal risk factors:**

**36 week review and delivery plan**

*If the latest viral load is not documented or on computer, the result can be obtained from the Regional Virus lab at 02890 63 2662 quoting the GUM clinic number, or contacting the virologist on-call at RGH during out-of-hours.*

**PERIPARTUM QUICK GUIDE**

- If the most recent HIV viral load is fully suppressed, and there are no relevant maternal risk factors at full term – then delivery as per non HIV infected woman.

- If the most recent HIV viral load is not suppressed – aim to deliver by C/section ASAP – if time permits, consult protocol & discuss with GUM re additional ARV intervention. All potentially required ARV drugs are available on site in the HIV antenatal drug pack.
• If a HIV positive woman presents in labour to a local maternity unit it may be inappropriate to transfer her to RJMH as it may delay prompt obstetric management (including ARV intervention). Transfer to RJMH can only take place with consultation and agreement of the RMDT.

SECTION 3: NEONATAL INPUT

First appointment with paediatrician to discuss: Date________________
(Ideally this should take place during the antenatal period)

Drug treatment for baby

Avoidance of breast feeding

Follow up testing of baby

Immunisations

Co-infections _________________________________

POST DELIVERY

Drugs for infant

Drugs commenced time____________ date______________

Day 1 blood sample from baby date____________

Maternal sample day 1 postnatal date____________

Appointment for Dr Tubman’s Tues Baby clinic* date______________

*This should be for 2 weeks post infant discharge and given to mother before discharge
VIROLOGY REQUEST
Congenital HIV transmission follow up
BABY SAMPLE

AFFIX LABEL OR ENTER DETAILS LEGIBLY
Send to: REGIONAL VIRUS LABORATORY, Kelvin Building, Belfast HSCT, Grosvenor Road, Belfast BT12 6BA. Direct Tel 02890 632662

<table>
<thead>
<tr>
<th>Forename/Initial</th>
<th>Surname/Initial</th>
<th>D.O.B</th>
<th>Male/Female</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Mother’s initials and DOB (or HPA sample reference number if known):

<table>
<thead>
<tr>
<th>Hospital No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Hospital | Consultant /GP | Ward / Clinic |
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

NB: please send a contemporaneous sample of maternal blood (EDTA) using the separate “Mother’s Sample” form.

FOR THE WARD Please tick appropriate box.

1. ☐ At Delivery - 2ml EDTA Blood from baby  
   Do not use Cord Blood

2. ☐ Follow up - 2ml EDTA Blood from baby (schedule: 6 Weeks, 3, 12 and 18 Months)

FOR THE LAB RECEIPTION

2ml EDTA Blood from Child  Lab Code {BHIC}

<table>
<thead>
<tr>
<th>Specimen type</th>
<th>Specimen Date</th>
<th>Lab use</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTA blood</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Take care that no blood contaminates the outside of the tube
- Specimen container lids should be well secured to prevent leakage in transit.
- Ensure that specimens are in a sealed plastic bag
- This form may be photocopied
**VIROLOGY REQUEST**

**Maternal HIV assessment**

**MATERNAL SAMPLE**

**AFFIX LABEL OR ENTER DETAILS LEGIBLY**

Send to: REGIONAL VIRUS LABORATORY, Kelvin Building, Royal Group of Hospitals Trust, Grosvenor Road, Belfast BT12 6BA. Direct Tel 02890 632662

<table>
<thead>
<tr>
<th>Female</th>
<th>Surname/Initial</th>
<th>Forename/Initial</th>
<th>D.O.B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Address</th>
<th>Hospital No.</th>
<th>NHS</th>
<th>Cat 2</th>
<th>Private</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Consultant /GP</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Ward / Clinic</th>
</tr>
</thead>
<tbody>
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<td></td>
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</tbody>
</table>

Note: Ideally a maternal blood will have already been checked for primer utility before HAART treatment, as post treatment bloods may be PCR negative. If it is suspected that this has not been done then please send maternal blood (EDTA) at delivery using this form.

**FOR THE WARD**

- [ ] During pregnancy - 5 ml EDTA Blood
- [ ] At Delivery - 5 ml EDTA Blood from Mother.

**FOR THE LABORATORY RECEPTION**

<table>
<thead>
<tr>
<th>Specimen type(s)</th>
<th>Specimen Date</th>
<th>Lab use</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTA blood</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specimen type(s)</th>
<th>Lab use</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTA blood</td>
<td></td>
</tr>
</tbody>
</table>

**Affix Category 3 sticker here**

- Ensure that specimens are in a sealed plastic bag
- Specimen container lids should be well secured to prevent leakage in transit
- This form may be photocopied
PROTOCOL FOR MANAGEMENT OF ANTENATAL SCREENING HIV RESULTS

This protocol sets out the responsibilities and actions required of each clinical area involved in the antenatal HIV screening process.

MATERNITY UNITS

• All women should be offered a screening test for HIV in early pregnancy or as soon as possible if booking after 20 weeks gestation or attending unbooked and requiring care.

• This test should be done along with the other routine infections screening tests and sent to Northern Ireland Blood Transfusion Service (NIBTS)

• For women booking after 20 weeks gestation the test along with other infections screening tests should be sent to Regional Virus Laboratory (RVL) using the late booking protocol and laboratory form*.

• Maternity Units should receive hard copies of all results within two weeks of the sample being taken.

• Hard copies of all results should be filed in the woman’s notes and recorded on the NIMATS/IT system.

• Maternity Units should employ failsafe systems to ensure all blood test results are accounted for and missing results followed up and acted on in an appropriate and timely manner.

Consent

The consent process outlined in the Infectious Diseases in Pregnancy Screening Consent Policy should be followed.

All women offered an antenatal HIV screening test should be informed of:

• the reasons for testing,
• HIV risk factors
• outcomes of a test
• possibility of a second test
• implications of a positive test result
• how their results will be recorded
• who will have access to their results

Negative Results

• Women should be informed of their negative HIV test result at their next hospital visit.

Positive Results

• RVL will notify the designated Trust leads of a positive HIV result initially by secure email and followed up with a hard copy. A receipt of email is required by RVL for failsafe purposes.

• The woman’s consultant/lead midwife will liaise with Genito Urinary Medicine GUM
to arrange a mutually suitable appointment time to see the woman and inform her of the result.

• The BHIVA guidelines for management should be followed

• All hard copies of results from RVL and NIBTS should be filed in the woman’s notes and recorded on NIMATS with the woman’s consent.

Equivocal Results

• RVL should send a secure email to the designated Trust Leads to request a second blood sample. Receipt of email by RVL is required for failsafe purposes.

• RVL should also request second blood sample on their hard copy report issued to the Maternity Unit. There is no requirement for this to be taken urgently therefore Units should manage it in a timely, appropriate way depending on gestation of pregnancy.

• Woman should be recalled for the second blood sample as instructed by RVL ‘HIV reactivity NOT CONFIRMED. Consider a repeat test in 2-3 weeks – which should be sent to virology’.

Women should be informed that occasionally there is a slight reaction within the HIV test. This, in almost all cases, does not indicate HIV infection but requires the blood to be retested using a second sample.

RECORDING DATA ON IT SYSTEMS

Staff should be aware of their duty to maintain confidentiality in accordance with Trust policies and the Data Protection Act 1998, when handling all results and recording them on IT systems. Professional advice regarding confidentiality, including computer held records can be found on the Nursing Midwifery Council website www.nmc.com; General Medical Council website www.gmc-uk.org; and in “The Data Protection Act 1998 – Legal Guidance” found at www.informationcommissioner.gov.uk.

NORTHERN IRELAND BLOOD TRANSFUSION SERVICE

• Sample is logged onto system when received and sent for testing.

Negative Result

• Negative result should be issued routinely on next working day to the Maternity Unit as per request form.

• Negative results should be recorded on the NIBTS IT link for Maternity Units to access.

Reactive Result

• NIBTS should forward the sample to RVL for confirmatory testing

• NIBTS should send patient information details to RVL

• Await confirmed sample result from RVL
• On receipt of confirmed result NIBTS should send out hard copy of result
  • Confirmed negative follow normal procedure
  • Confirmed positive send copy to woman’s consultant obstetrician and nominated lead midwife.

REGIONAL VIROLOGY LABORATORY

Office protocol for all specimens received from NIBTS for confirmatory testing

The specimen received from NIBTS will be allocated an RVL specimen number and logged in as a routine specimen. If an NIBTS specimen number (e.g. BTS 123456) is provided this should be entered into the clinical details section of LabCentre.

Confirmatory testing of HIV results

All antenatal HIV samples screened reactive by NIBTS will be referred to RVL and tested by 2 assays – Abbott Architect (4th generation), and Vidas HIV DUO (4th generation).

Laboratory Protocol

There will be two outcome pathways for this testing and all results will go through the authorisation queue. For all scenarios an appropriate memo will be added. Screening test results will be reported by hardcopy to NIBTS. Confirmed test results will be reported both to the clinic by e-mail and by hardcopy to NIBTS.

(1) NONCONFIRMED HIV REACTIVITY

If HIV reactivity does not confirm i.e. remains negative in one or both assays a hard copy will be issued to NIBTS with an explanatory comment\(^a\) explaining the significance of the non-confirmed reactivity.

(2) CONFIRMED HIV SPECIFIC HIV REACTIVITY

Where both 4th generation assays are positive, an additional INSTI Anti-HIV-1/HIV-2 and immune-blot assay, HIV 1+2 BiSpot Immunocomb II will be performed. If reactivity is not confirmed a hard copy with an explanatory comment\(^a\) will be issued to NIBTS. If HIV reactivity is confirmed a hard copy with an explanatory comment\(^b\) will be issued to NIBTS advising referral for GUM pinion. Virology will also e-mail the clinic and GUM to inform them of the new case.

\(^a\) HIVNC HIV reactivity NOT CONFIRMED. Consider a repeat test in 2-3 weeks – which should be sent to virology.

\(^b\) HIVC Results indicate infection with Human Immunodeficiency Virus. This reactivity needs a GUM referral.