Guidelines for the management of HIV positive pregnant women in Northern Ireland

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HSC Public Health Agency

Title	Guidelines for the management of HIV positive pregnant women in Northern Ireland.
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Guideline contributors	The guideline was sent regionally for comments during its development to Trust Antenatal Screening Co-Ordinators, Lead midwives, Obstetricians, Paediatricians, Neonatologists, GUM Consultants, Pharmacy Leads and Laboratory managers. Thanks to everyone who sent back comments or contributed in any way. Service users were given an opportunity to input into the guidelines via Positive life HIV support group.
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Review date	Updated by Lorna Hawe 10/07/23: - Appendix 11 has been updated to correct the dose of Raltegravir oral suspension from 20mg /mL to 10mg/mL, Page 36 – 13.3.5 added in brackets (2 purple topped bottles). Appendix 9 - Infant blood form added as a title. Appendix 10 - Maternal blood form added as a title. The full guidelines will be reviewed in 2025 or sooner if new evidence changes practice.

Contents

1.0 Glossary

ANSC	Antenatal Screening Co-Ordinator. There is an antenatal screening co-ordinator appointed to each of the 5 trusts across Northern Ireland who is responsible for co-ordinating the care of HIV positive pregnant women and their babies.
CD4 cells also called T cells or CD4+Tcells	These are the 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. The normal CD4 count for an adult is 500-1200 cells /mm^3.
GUM	Genito Urinary Medicine department. HIV care and treatment is generally provided by the Belfast Health and Social Care Trust (BHSCT), at the GUM department in Royal Group of Hospitals- Belfast site, but may be provided locally if local services are available.
HAART	Highly Active Antiretroviral Therapy - 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.
HBIG	Hepatitis B immunoglobulin (HBIG) is a human immunoglobulin that is used to prevent the development of hepatitis B. It will be given to babies of mothers who have a high infectivity status.
HIV	Human Immunodeficiency Virus belongs to a group of viruses called 'retroviruses'. HIV attacks the immune system leaving the infected person vulnerable to serious infections and cancers. 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.
IDPS	The infectious diseases in pregnancy screening programme, involves the screening of pregnant women for HIV, hepatitis B, syphilis and rubella susceptibility.
IRIS	Immune inflammatory syndrome (IRIS) is deterioration of a pre-existing illness following abrupt improvement in an individual's immune function. It is classically seen in HIV/AIDS patients following initiation of HAART.
LOG reduction	"Log" stands for logarithm, which is the exponent of 10. For example, Log 2 represents 10^2 or 10 x 10 or 100. Log reduction stands for a 10 fold (or one decimal) or 90% reduction in numbers of live viruses.

	Another way to look at it is: 1 Log reduction would reduce the number of viruses by 90%. This means, for example, that 100 viruses 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*
MHHR	The Maternity Hand-Held Records are regional notes that pregnant women will carry between appointments. They are used to communicate the story of client care between care providers and also contain relevant educational information for the women.
MTCT	Mother-To-Child Transmission of HIV, also called perinatal or vertical transmission, occurs when HIV is passed from a HIV positive mother to her baby either during the antenatal period, intra-natal period or in the postnatal period through breastfeeding. The risk of transmission in the absence of intervention ranges from 15 - 45%[1]; however, this risk can be reduced to < 5% through appropriate treatment and interventions.
NIMATS	Northern Ireland Maternity System is a web based electronic system used regionally to capture geographical and clinical data on pregnant women and their babies. This includes results of screening tests such as HIV.
PCR	Polymerase Chain Reaction test. This is a test used to detect HIV genetic material called RNA in the blood. Also known as the viral load test.
PEP	Post exposure prophylaxis - the term used for the antiretroviral treatment given to the baby after delivery to reduce the risk of MTCT.
PROM	Premature rupture of membranes refers to membrane rupture after 37 weeks gestation, before the onset of labour.
PPROM	Preterm PROM (PPROM) refers to PROM before 37+0 weeks gestation. It is responsible for, or associated with, approximately one-third of preterm births and is the single most common identifiable factor associated with preterm delivery. [2]
RJMH	Royal Jubilee Maternity Hospital where the RMDT is sited. Care can be offered to low risk women in their local unit depending on local policies, however they can still be referred for care in RJMH if the woman prefers this. This should be discussed and agreed with the RMDT and the local consultants.

[1] http://www.who.int/hiv/topics/mtct/about/en/

[2] https://www.uptodate.com/contents/preterm-prelabor-rupture-of-membranes-management#!

RMDT	Regional Multidisciplinary Team consists of specialist professionals from Genitourinary Medicine (GUM), obstetrics, midwifery, specialist pharmacy, HIV counsellors, HIV nursing, neonatology and paediatric infectious diseases within the Royal Hospital site.
RVL	The regional virus laboratory is located in the Kelvin Building, on the BHSCT / Royal Hospitals site, and is the only UKAS-accredited provider of clinical virology testing services for hospitals, GPs and public health professionals in Northern Ireland.
RNA	Ribonucleic Acid (RNA) is the genetic material that makes up certain viruses, like HIV. An HIV RNA test searches for the genetic material of HIV rather than antibodies or antigens to it, allowing for earlier detection (in as little as 9-11 days after exposure).
Viral load	The amount of HIV RNA in the blood. One of the goals of HAART in pregnancy is to reduce the viral load, reducing the risk of MTCT of the HIV virus. The RVL 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 "<80 IU/ml (Log value <1.7)". This equates to approximately <50 HIV RNA copies/ml. • 1 IU/ml =0.58 HIV RNA copies/ml, 1 HIV RNA copy =1.74 IU.

2.0 Foreword

These Northern Ireland regional guidelines have been developed to provide best practice guidance on screening for human immunodeficiency virus (HIV) in pregnancy; treatment and management of women screened positive for HIV during pregnancy or post-delivery; and postpartum management of women and their babies. The scope of the document includes guidance on the use of Highly Active Antiretroviral Therapy (HAART) to prevent mother to child transmission (MTCT) of HIV; and for the welfare of the woman and her baby. The guidelines are aimed at clinical professionals directly involved with and responsible for the care of pregnant women screened positive for HIV and their babies.

The guidelines are in keeping with:

British HIV Association (BHIVA) guidelines for the management of HIV infection in pregnant women 2018(2019 second interim update).[3]

2017 Childrens HIV association (CHIVA) Standards of Care for Infants, Children, and Young People living with HIV (Including infants born to mothers with HIV). [4]

National Health Service (NHS) Infectious Diseases in Pregnancy Screening Programme Laboratory Handbook 2016 to 2017.[5]

Public Health England (PHE) Infectious Diseases in Pregnancy Screening Standards valid for data collected from 1st April 2018 (Updated 26th July 2019).[6]

2.1 Key changes from the 2013 document.

- Previously pregnant women only started treatment around 22-24 weeks gestation, whereas current recommendations are that women will commence treatment as soon as possible after diagnosis, in the second trimester, or earlier if the viral load is >174,000 IU/mL (>100,000 HIV RNA copies /mL).

- Women may have stopped treatment following delivery previously whereas, they will now be advised to remain on HAART for life.

[3] https://www.bhiva.org/PREGNANCY-GUIDELINES

[4] https://www.chiva.org.uk/files/5215/3987/5455/CHIVA_STANDARDS_2017.pdf

[5] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/539828/NHS_Infectious_Diseases_in_Pregnancy_Screening_Programme_Laboratory_Handbook_2016_2017_with_gateway_number.pdf

[6] https://www.gov.uk/government/publications/infectious-diseases-in-pregnancy-screening-programme-standards/infectious-diseases-in-pregnancy-screening-standards-valid-for-data-collected-from-1-april-2018

- Although breastfeeding is still not recommended there is advice included on how to support a low risk mother whose viral load is well controlled and who chooses to breastfeed against advice.

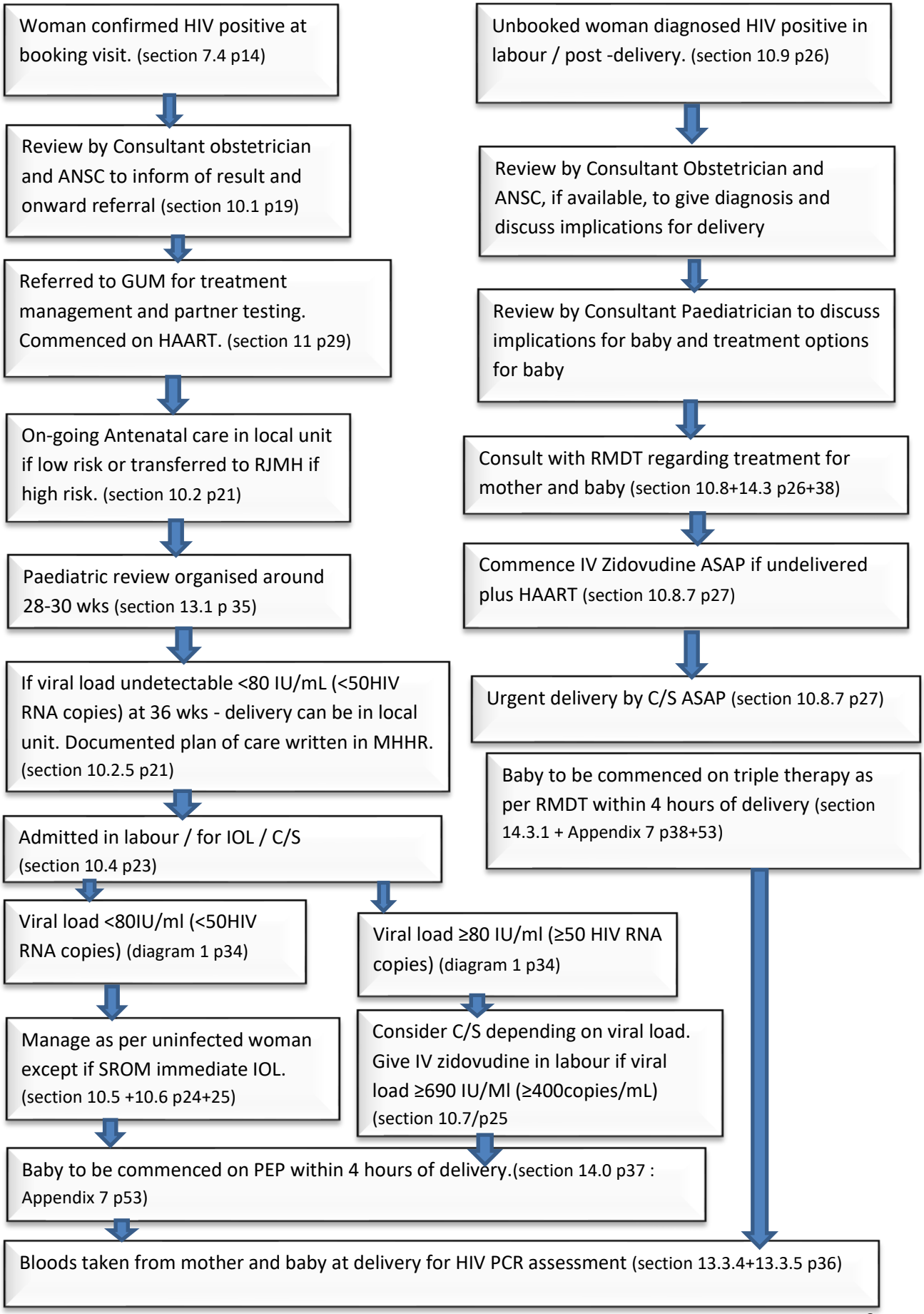
- Previously most mothers would have been advised to transfer care to Royal Jubilee Maternity Hospital (RJMH) for delivery, whereas the Regional Multidisciplinary Team (RMDT) have now advised that low risk women whose viral load is well controlled on HAART, can be delivered in their local unit unless they request to be transferred to the RJMH.

- The following women remain a higher risk group and should still be transferred to the regional unit for ongoing care: -

    a) Co-infection with Hepatitis B or C.
    b) 12 weeks on HAART with no significant reduction in viral load.
    c) Non-compliance with medication.
    d) Late booking (>30 weeks) with very high viral load.
    e) Other maternal/fetal indications that would warrant delivery in the regional unit e.g. fetal anomaly.
    f) Patient request for the purpose of confidentiality.

- Previous recommendations were that all babies would have been treated with Post exposure prophylaxis (PEP) for 4 weeks postnatally whereas new advice is that babies born to very low risk mothers may stop PEP after 2 weeks. This will be dependent on the initial HIV PCR result being negative.

2.2 Management summary for women diagnosed with HIV in pregnancy.



3.0 Aims

3.1 To offer and recommend screening to all eligible pregnant women to enable early detection and treatment of HIV in pregnancy in order to significantly reduce the risk of mother-to-child transmission (MTCT).

3.2 To ensure that all eligible pregnant women in Northern Ireland receive high quality up to date information in the appropriate easy to understand language on HIV testing as part of the Infectious Diseases in Pregnancy Screening (IDPS) programme to enable them to make an informed choice about their screening options.

4.0 Key objectives

4.1 To ensure that HIV infection screening is offered and a result available for all pregnant women who: -

i) Book for maternity care within a Health and Social Care Trust (HSCT) in Northern Ireland, excluding women who miscarry between booking and testing; or transfer in from outside Northern Ireland and have a result from a screening test performed elsewhere in the United Kingdom (UK) or Southern Ireland in this pregnancy.

ii) Present unbooked to a maternity unit in Northern Ireland; including those presenting in labour or immediately post-delivery without documented evidence of HIV testing in the current pregnancy**.**

4.2 To ensure appropriate follow-up and treatment, where necessary of: -

i) Pregnant women identified with HIV infection.

ii) New-born infants of women identified with HIV during pregnancy.

iii) Sexual contacts of women identified with HIV infection.

iv) Other children of women identified with HIV infection.

4.3 To ensure that women declining screening are properly counselled by the Antenatal Screening Co-Ordinator (ANSC) and reoffered the test prior to 20 weeks gestation. Some women may still choose not to be screened for HIV and it is important that this choice is respected, although an offer to test the baby at delivery should be made.

4.4 To provide assurance that national standards are met in relation to the screening programme. [6]

5.0 Background

HIV is a virus which infects the cells of the immune system, specifically the CD4 cells destroying or impairing their function. Without treatment, HIV

advances in stages, overwhelming the immune system and getting worse over time.

The three stages of HIV infection are: (1) acute HIV infection (2) clinical latency and (3) Acquired Immunodeficiency Syndrome (AIDS).[7]

MTCT of HIV can occur during pregnancy, at the time of birth, or through breast feeding. The risk of transmission in the absence of intervention ranges from 15 - 45%.[8] This risk can be reduced to < 5% through appropriate treatment and interventions.

The HIV RMDT is based at the BHSCT / Royal Hospitals site and includes health professionals from Genitourinary Medicine (GUM), obstetrics, neonatology, paediatric infectious diseases, midwifery, specialist pharmacy, HIV counsellors, and HIV nursing.

Good communication and liaison between members of the RMDT, the mother and local maternity services is key to ensuring the best possible outcome for the mother and her baby.

6.0 Pathway for HIV screening in pregnancy

	Pathway for HIV screening in pregnancy	**Timescale**
6.1	All pregnant women in Northern Ireland (excluding women who miscarry between booking and testing, or transfer in from outside Northern Ireland and have an HIV screening result from a test performed elsewhere in the UK or Southern Ireland in this pregnancy) 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. (NICE guidelines).[9]	Usually between 10 - 13 weeks gestation.
6.2	Women should also be offered screening for hepatitis B syphilis and rubella immunity at their booking visit.	
6.3	Women from the following categories should also be offered screening for hepatitis C: - • Current or past drug users who have shared drug equipment or paraphernalia. • Women who have received unscreened blood transfusions pre-1991 in the UK. • Women who have had unsterile tattoos or body piercings especially in non UK countries.	

[7] https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids
[8] http://www.who.int/hiv/topics/mtct/about/en/
[9] https://pathways.nice.org.uk/pathways/antenatal-care-for-uncomplicated-pregnancies

	• If a woman has clinical features of possible hepatitis e.g. jaundice or non-specific and unexplained symptoms. • If a woman has abnormal liver function tests.	
6.4	The leaflet "Protecting you and your baby" should be given in the appropriate language to all women eligible for screening[10]. Consideration should be given to women with learning disabilities to ensure that they are given the information in an appropriate manner to allow understanding.	Prior to the offer of the screening test.
6.5	All women should be informed of the occasional need for a repeat test due to false positive results and of the implications of a confirmed positive test result.	Prior to screening for HIV.
6.6	The consent form in the Maternity Hand-Held Records (MHHR) should be completed.	Prior to screening for HIV.
6.7	The screening test should be sent to the Northern Ireland blood transfusion service (NIBTS) for testing.	< 20 weeks gestation.
6.8	The screening test should be sent to the Regional Virus Laboratory (RVL) using the "late booking in pregnancy" laboratory form - see attached link.[11]	≥20weeks gestation or presenting unbooked in labour.
6.9	Women declining testing in the antenatal period should be referred to the ANSC for expert counselling and formal reoffer of the test.	Following the booking visit.
6.10	The ANSC should review women who decline at a face to face meeting if possible.	By 20 weeks gestation.
6.11	If a woman reaches delivery without having accepted testing for HIV the test should be reoffered again.	In labour/after delivery.
6.12	Where a mother continues to decline testing and her HIV status remains unknown at delivery, an offer to test the baby's HIV status should be made. (Cord bloods can be used for this).	Within 4 hours of birth.

[10] https://www.publichealth.hscni.net/publications/protecting-you-and-your-baby-blood-tests-your-first-antenatal-visit

[11] http://www.rvl-belfast.hscni.net/wp-content/uploads/2019/04/Late_Booking_in_Pregnancy_Form_040319b.pdf

6.13	Maternity Units should employ failsafe systems to ensure that a result has been received for every woman screened and that any missing results are followed up and acted on in an appropriate and timely manner.	Within 2 weeks of the screening date.
6.14	Rejected samples should be repeated.	Within 10 working days of a repeat request being received from the laboratory.
6.15	Where a woman, who has screened negative, discloses that her partner is HIV positive, a reoffer of HIV screening can be made later in pregnancy if considered necessary.	Before 36 weeks.
6.16 Information sharing		
6.16.1	Professionals should refer to their individual professional guidance and the data protection act 2018[12] before sharing information with other professionals about the HIV status of affected individuals or their partners.[13] [14] [15]	Prior to 36 weeks.
6.16.2	Information regarding an individual's/partner's HIV status may be shared without consent if it is in the best interest of the mother and baby to do so and if by not doing so the baby would be at increased risk of MTCT transmission of HIV. However, it should be disclosed to the person that this information will be shared and why.	Prior to 36 weeks.

7.0 Result outcomes

7.1 Screen negative result

A negative test for HIV antigen and/or HIV antibody usually indicates that a person does not have an HIV infection. However, a negative screening test means only that there is no evidence of infection at the time of the test. It is important for those

[12] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/711162/2018-05-23_Factsheet_1_-_Act_overview.pdf

[13] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/protecting-children-and-young-people/confidentiality-and-sharing-information

[14] https://www.nmc.org.uk/globalassets/sitedocuments/data-protection/data-sharing-policy.pdf

[15] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/721581/Information_sharing_advice_practitioners_safeguarding_services.pdf

who are at increased risk of HIV infection, such as intravenous drug users, commercial sex workers and women having unprotected sex with different partners during pregnancy, be rescreened later in pregnancy (28-32 weeks or later depending on ongoing risk) to check for exposure to the virus.

7.2 False negative result

If someone is screened with an HIV antibody test too soon after exposure to the virus, the result may be negative despite the fact that the person is infected (false negative). Although the use of fourth generation antibody/antigen HIV tests has reduced the window period (the period between the onset of HIV and the appearance of detectable antibodies to the virus) to 18 days a repeat request may still be necessary between 4 - 12 weeks following a high-risk exposure.

7.3 Screen reactive result

This is when HIV antigens and/or antibodies are detected in serum using a screening assay (fourth generation) test for HIV antibody AND p24 antigen simultaneously. All samples which are screened reactive should be confirmed using confirmatory assays. Specimens screening reactive in NIBTS <20 weeks will be referred to RVL for further confirmatory testing. Late bookers screening reactive in RVL ≥20 weeks or unbooked in labour will follow the RVL laboratory testing algorithm.

7.4 Confirmed reactive result

A confirmed reactive result is when a screened reactive test has been confirmed as being positive. All new HIV diagnoses should only be made following appropriate testing with confirmatory assays. (Apart from results received in labour).
There is a requirement for three independent assays, two of which should be fourth generation assays and at least one assay should have the ability to distinguish HIV-1 and HIV-2.
HIV RNA assays may be used to identify acute HIV infection, for example, where screening assays are positive and antibody only tests are negative.
All new HIV diagnoses should have a second blood specimen sent for confirmation of the individual's identity.

7.5 Unconfirmed reactive screening results/ false positive.

If HIV reactivity in a screening assay does not confirm in additional tests i.e. remains negative in one or both fourth generation assays a report will be issued by RVL requesting a repeat specimen in 2-3 weeks - to be sent directly to the RVL. The reactivity in the screening assay is most probably a false positive. A second sample is tested to exclude early seroconversion. The RVL will provide interpretation of all laboratory results and can be contacted on 07889086946 24/7 for advice.

8.0 Processing of results – laboratory responsibilities

8.1 Tested in NIBTS< 20 weeks gestation.		
8.1.1	**Screen negative results in NIBTS**	**Timescale**
	Negative results will automatically download from Northern Ireland Blood transfusion service (NIBTS)	As soon as the result has been verified by NIBTS.

	to the Northern Ireland Maternity System (NIMATS).	
	Hard copies of all results should be issued by NIBTS routinely to the maternity unit as per the request form.	Within 8 working days of sample receipt in the laboratory.[5]
	The results should be communicated to the woman by the midwife / clinician and filed in her notes with permission.	At her next antenatal visit.
8.1.2	**Initial screen reactive result in NIBTS**	
	In the event of a screen reactive result in NIBTS the sample should be forwarded to RVL for confirmatory testing.	As soon as possible.
8.1.3	**Screened reactive results received from NIBTS for confirmatory testing in RVL**	**Timescale**
	The office protocol for all antenatal specimens received from NIBTS for confirmatory testing should be followed. These samples should be prioritised.	On receipt of specimen.
	The specimen received from NIBTS will be allocated an RVL specimen number and logged in as a routine specimen.	On receipt of specimen.
	If an NIBTS specimen number (e.g. BTS 123456) is provided this should be entered into the clinical details section of LabCentre.	On receipt of specimen.
	Samples for confirmatory testing will be tested by 3 assays – Roche HIV combi PT (4th generation), and Biomerieux Vidas HIV DUO (4th generation) and an antibody only INSTI Anti-HIV-1/HIV-2 assay.	On receipt of specimen.
8.1.4	**Non-confirmed HIV reactivity in RVL**	
	If HIV reactivity **IS NOT** confirmed i.e. remains negative in one or both 4th generation assays, NIBTS should be notified electronically (via Labcentre) with an explanatory comment – "**HIVNC** HIV reactivity NOT CONFIRMED. Consider a repeat test in 2-3 weeks – which should be sent directly to virology."	Within 8 working days of sample receipt in the NIBTS laboratory.

8.1.5	**Confirmed HIV reactivity in RVL**	
	If HIV reactivity **IS** confirmed, NIBTS should be notified electronically (via email to TMResults@nibts.hscni.net) with an explanatory comment – "**HIVC** Results indicate infection with Human Immunodeficiency Virus. This reactivity needs a GUM referral."	Within 8 working days of sample receipt in the NIBTS laboratory.
	A NEW diagnosis of HIV will be emailed from NIBTS to the ANSC via generic email (Appendix 1) (Acknowledgement of this email should be sent).	Within 8 working days of sample receipt in the NIBTS laboratory.
	A hard copy of the positive result should also be sent to the ANSC / named consultant.	Within 8 working days of sample receipt in NIBTS.

8.2 Late booking tests ≥20 wks gestation, received and tested in RVL		
8.2.1	**Negative results**	**Timescale**
	These results will **not** automatically download onto NIMATS at present.	
	A hard copy result will be issued to the maternity unit as per the request form.	Within 8 working days of sample receipt in the RVL laboratory.
	The result will have to be manually inputted onto the NIMATS system in the record results section, by the ANSC.	On review of the result on lab links/receipt of the hard copy result.
	The results should be communicated to the woman by the midwife/clinician and filed in her notes with permission.	At her next antenatal visit.
8.2.2	**Initial screen reactive result**	
	Samples for confirmatory testing will be tested by 3 assays – Roche HIV combi PT (4th generation), and Biomerieux Vidas HIV DUO (4th generation) and an antibody only INSTI Anti-HIV-1/HIV-2 assay.	Following initial reactive screen.
8.2.3	**Confirmed positive result**	
	A confirmed positive result will be communicated to the ANSC using generic email accounts	Within 8 working days of sample receipt in the RVL laboratory.

	(Appendix 1). (Acknowledgement of this email should be sent).	
	A hard copy result should be issued to the ANSC/ clinician.	Within 8 working days of sample receipt in the laboratory.
8.2.4	For unbooked women tested on admission in labour a confirmed positive result should be phoned through to labour ward.	Within 4 hours of sample being taken.

8.3 Unconfirmed reactive result		
8.3.1	NIBTS / RVL should request a second blood sample in 2-3 weeks' time, on their hard copy report issued to the Maternity Unit.	Within 8 working days of sample receipt in the laboratory.
8.3.2	The woman should be informed of the need for a repeat sample and should be reassured and informed that occasionally non-specific reactivity can occur in the HIV screening test possibly due to antibodies that cross react with the HIV test. This, in almost all cases, does not indicate HIV infection but requires the blood to be retested using a second sample.	At a face to face meeting within 10 days of result receipt by maternity services.
8.3.3	Women should be recalled for the second blood sample as instructed by NIBTS / RVL.	Usually in 2-3 weeks' time.
8.3.4	This repeat sample should be sent directly to RVL using the late booking in pregnancy/confirmatory sample form.[16]	When sample is repeated.

[16] http://www.rvl-belfast.hscni.net/wp-content/uploads/2019/04/Late_Booking_in_Pregnancy_Form_040319b.pdf

9.0 Management of HIV positive pregnant women.

The best clinical practice should be based on most up to date national guideline produced by BHIVA. [3]

The most important factor that predicts the risk of mother to child transmission is the level of HIV virological suppression at delivery.

The aim of treatment is to have complete HIV virological suppression at delivery. If this is achieved, and in many cases, it is, then without other complicating factors 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) <80 IU/ML (<50 HIV RNA copies/ML) are considered to have complete HIV suppression.

For the majority of cases presenting early, complete suppression should be achievable by delivery. This depends greatly on the woman's ability to adhere to her HAART. Support in coping with her situation; addressing drug tolerance and side effects; patient education and simple aids like a pill box; have all been shown to improve adherence.

The GUM service will advise on the management of HIV in pregnancy.

The Obstetric consultant will advise on the management of pregnancy and anticipated mode of delivery.

Paediatric /Neonatology services will advise on management of the baby following delivery.

10.0 Obstetric/midwifery management

(Refer to BHIVA guidelines section 8, p69)[3]

10.1 Following receipt of a positive HIV result		Timescale	Comment
10.1.1	Arrange urgent review appointment with named Obstetric Consultant + ANSC / Deputy ANSC. (Organise interpreter if necessary).	Within 10 days of receipt of result - Standard 5-IDPS[6]	
10.1.2	Contact GUM services either local (if HIV GUM services available locally) or regional and provisionally arrange an urgent appointment for both the woman and her partner.	Prior to mother attending the above appointment.	
10.1.3	The woman should be informed of her HIV diagnosis, in person by the Obstetric Consultant, with the ANSC / deputy in attendance and using interpreters if necessary. She should then be encouraged to tell her partner if present, but this should only be done with her consent.	Within 10 days of the positive result being received by maternity services.	
10.1.4	On line links to information about HIV should be provided or printed information in the appropriate language, depending on the woman's preference.[17]	At initial review appointment in maternity services.	
10.1.5	Bloods should be taken for confirmatory testing using a red/yellow top bottle and sent using the late booking in pregnancy/confirmatory sample form.[11] If a viral load is deemed necessary an extra ETDA purple top sample should be sent with the time taken and viral load request clearly stated on the form and the bottle, as it must reach the laboratory within 24 hours to avoid rejection.	At initial review appointment in maternity services.	
10.1.6	Offer prearranged appointment at GUM and stress the importance of attending this appointment. The woman should be advised to take her maternity hand-held records (MHHR) to this appointment.	At initial review appointment in maternity services.	
10.1.7	The GUM appointment should be confirmed initially by phone and then followed up by the referral form (Appendix 2) either emailed to a specific local consultant if HIV GUM services are	Following the initial review appointment in	

[17] http://www.aidsmap.com/translations

	available locally or posted to: - GUM consultant, The Royal Hospitals, 274 Grosvenor Road, Belfast BT12 6BA.	maternity services.	
10.1.8	Consent should be obtained from the woman before any information about her diagnosis is uploaded unto her Northern Ireland Electronic Care Record (NIECR). This should be encouraged in order to ensure that those people involved in her care can provide safe and effective health care.	At initial review appointment in maternity services, prior to uploading a referral/ letter onto ECR.	
10.1.9	Low risk women should be booked for delivery in their local Trust under close consultation with the RMDT, unless they request to transfer care to RJMH.	At initial review appointment in maternity services.	
10.1.10	High risk women from the following categories should be transferred to RJMH for ongoing care: - • Co-infection with Hepatitis B or C. • Late booking (>30 weeks) with very high viral load. • Other maternal/fetal indications that would warrant delivery in the regional unit e.g. fetal anomaly. • Patient request for the purpose of confidentiality.	At initial review appointment in maternity services.	
10.1.11	If the woman chooses to transfer care to the regional unit, a referral form (Appendix 2) should be sent to the RJMH Obstetric Consultant 274 Grosvenor Road, Belfast BT12 6BA.	Following initial review appointment in maternity services.	
10.1.12	The HIV positive results should be inserted in the woman's MHHR and inputted onto NIMATS by the ANSC or her deputy, with the woman's consent.	At initial review appointment in maternity services.	
10.1.13	The Antenatal management plan (Appendix 3) should be completed and inserted into the MHHR with consent.	At initial review appointment in maternity services.	
10.1.14	Women diagnosed late in the antenatal period (≥20^{+0} weeks gestation); diagnosed in labour; or immediately post-partum should have an urgent referral organised with the GUM team. The relevant team members should be contacted via the contact numbers (Appendix 4).	Following receipt of diagnosis.	

10.2 Follow on antenatal care		Timescale
10.2.1	An appointment should be arranged for the woman with the consultant neonatologist / paediatrician who will be reviewing the baby postnatally, to discuss care following delivery of the baby, including treatment and testing of the baby, infant feeding and any concerns voiced by the woman.	Around 28-30 weeks.
10.2.2	A discussion should take place with the woman about her proposed obstetric management including issues such as antenatal monitoring of mother and baby, obstetric interventions in labour, mode of birth and the avoidance of breastfeeding.	Throughout pregnancy and before delivery.
10.2.3	The importance of taking the HAART medications should be stressed.	Throughout pregnancy.
10.2.4	The obstetric team should have the following basic understanding of the virological response to HAART: - ○ It takes time for any antiretroviral regime to work – a typical expectation might be approximately 1.5 log reduction in viral load 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 HAART. This will aid the anticipation of any deviation and help pre-plan the peri-partum requirement and the mode of delivery.	Throughout pregnancy
10.2.5	For women taking HAART, a decision regarding recommended mode of delivery should be made after review of plasma HIV viral load results. This should be discussed with the woman and a plan of care documented in her MHHR.	At around 36 wks.
10.2.6	Care should be transferred to the RJMH for women in the following categories: - a) Co-infection with Hepatitis B or C b) 12 weeks on HAART with no significant reduction in viral load c) Non-compliance with medication d) Other maternal/fetal indications that would warrant delivery in the regional unit e.g. fetal anomaly. e) Maternal choice.	At any stage throughout the antenatal period.
10.2.7	Regular communication regarding changes in the obstetric care plan, or newly identified obstetric risk factors, should be made via secure email or telephone if	Throughout pregnancy.

	more urgent, to all the health professionals involved in her care, in particular the GUM team if it will affect the care plan outlined by them.	
10.2.8	For women, where complete virological suppression is **unlikely**, the individualised care plan should be jointly decided with the GUM team, with reference to best practice based on BHIVA guidelines.	Ongoing.
10.2.9	Each Maternity Unit should hold an emergency HIV drug pack containing the drugs that a woman and her infant may require. **Ensure this pack is regularly checked to ensure stock is intact and in date**. Clinicians should refer to MEDUSA Injectable medicines guide for the preparation of the Zidovudine (Appendix 5).	Ongoing.
10.2.10	All women should be strongly advised by the Obstetric consultant and RMDT 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.	Throughout pregnancy.

10.3 HIV and hepatitis virus co-infection (Refer to BHIVA guidelines section 7, p57) [3]		**Timescale**
10.3.1	HIV positive women co-infected with hepatitis should be referred to the RMDT for ongoing management of care and delivery.	On diagnosis of co-infection.
10.3.2	The woman should be referred to the hepatologist in the RVH.	Within 10 days of a hepatitis diagnosis.[6]
10.3.3	Confirmation of viraemia with quantitative HBV DNA, 'e' antigen status as well as hepatitis A virus (HAV), hepatitis C virus (HCV) and hepatitis D virus (HDV) screening; and tests to assess hepatic inflammation/fibrosis and liver function are recommended. (Hepatology will perform these tests). GUM will perform Hepatitis C screening as part of their full sexual health screen.	On diagnosis of a new HBV infection.
10.3.4	Liver function tests (LFTs) should be repeated to detect evidence of hepatotoxicity or immune inflammatory syndrome (IRIS).	At 2 and 4 weeks after commencing HAART and then monitored regularly throughout pregnancy and postpartum.

10.3.5	For treatment options refer to BHIVA guidelines (section 7.1.4 - 7.1.8, p 58). [3]	
10.3.6	In the absence of obstetric complications, normal vaginal delivery can be recommended if the woman has fully suppressed HIV viral load on HAART, irrespective of HBV viral load.	
10.3.7	Selective neonatal immunisation with or without hepatitis B immunoglobulin (HBIG) - depending on infectivity status - should commence following delivery.	Within 24 hours of delivery, but preferably within 4 hours of birth and subsequently at 1 month and 12 months of life.
10.3.8	The national infant Hepatitis B vaccination schedule (HBV) schedule should also be followed. [18]	At 2, 3 and 4 months of life.

10.4 On admission in labour / induction of labour or for planned Caesarean section, for women well controlled on HAART.		**Time scale**
10.4.1	Follow the plan of care documented in the MHHR and liaise with the RMDT regarding her care if necessary.	On admission.
10.4.2	Inform the on-call Consultant Obstetrician	On admission.
10.4.3	Inform the on call Neonatal / Paediatric registrar. The on-call consultant should be informed during normal working hours and review arranged.	If in labour or delivered.
10.4.4	Inform the ANSC.	During normal working hours.
10.4.5	All delivery suites should ensure that they are equipped with appropriate blunt needles, drapes, gloves, visors, etc. for operative procedures.	In preparation for delivery.
10.4.6	Staff should adhere to standard precautions against infection. Refer to the regional infection prevention and control manual.[19]	When caring for the woman.

[18] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/740420/Hexavalent_combination_vaccine_guidance_routine.pdf

[19] https://www.niinfectioncontrolmanual.net/

10.5 Management of premature rupture of membranes (PROM) at term (Refer to BHIVA guidelines section 8.3, p74)[3]		**Plan of care**
10.5.1	In all cases of PROM at term.	Delivery should be expedited with an aim to deliver within 24 hours.
10.5.2	**<80 IU/mL** (<50 HIV RNA copies/mL) -last measured maternal HIV viral load.	Immediate induction of labour / augmentation of labour **is recommended**, with a low threshold for treatment of intrapartum pyrexia.
10.5.3	**80-690 IU/mL** (50–399 HIV RNA copies/mL) - last measured maternal HIV viral load.	Immediate Caesarean section **should be considered** following discussion with the on-call GUM consultant. Tel via switchboard: - 028 90 240 503.
10.5.4	**≥690 IU/mL <1740 IU/mL** (≥400<1000 HIV RNA copies/mL) – last measured maternal HIV viral load.	Immediate Caesarean section **is recommended** and intrapartum intravenous zidovudine infusion **can be considered**.[3]
10.5.5	**>1740 IU/mL** (>1000 HIV RNA copies/mL) – last measured maternal HIV viral load.	Immediate Caesarean section and intrapartum intravenous zidovudine **is recommended.** (During labour and delivery zidovudine should be administered intravenously at 2 mg/kg bodyweight given over one hour followed by a continuous intravenous infusion at 1 mg/kg/h until the umbilical cord is clamped).

10.6 Management of premature pre-term rupture of membranes (PPROM) (refer to BHIVA guidelines section 8.3.5-6, p75) [3]		**Plan of care**
10.6.1	≥34 weeks and ≤37 weeks.	Same management as term PROM except women will require group B streptococcus prophylaxis in line with national guidelines.[20]
10.6.2	<34 weeks.	• Intramuscular steroids should be administered in accordance with national guidelines.[21] • Virological control should be optimised. • There should be multidisciplinary discussion about the timing and mode of delivery. • If maternal HIV viral load is not fully suppressed prescribe and start the following ASAP: - Nevarapine 200mg stat, Tenofovir 490mg stat, Raltegravir 400mg BD (if not already started). • Give IV zidovudine throughout labour and delivery at 2 mg/kg bodyweight given over one hour followed by a continuous intravenous infusion at 1 mg/kg/h until the umbilical cord is clamped.

10.7 Recommended mode of birth for women on HAART (BHIVA guidelines section 8.2, p70)[3]		**Mode of birth**
10.7.1	**<80 IU/mL** (<50 HIV RNA copies/mL) plasma viral load at 36 weeks, and in the absence of obstetric contraindications.	A planned vaginal delivery is recommended.
10.7.2	In women for whom a vaginal delivery has been recommended and labour has commenced.	Obstetric management should follow the same guidelines as for the HIV-negative population. Amniotomy,

[20] https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.14821
[21] https://www.nice.org.uk/guidance/ng25/chapter/Recommendations#maternal-corticosteroids

		fetal scalp electrodes, fetal blood sampling, and episotomy can all be performed. If an instrumental delivery is necessary a low cavity traction forceps delivery is preferred to a vacuum assisted delivery, as it is associated with lower rates of fetal trauma.
10.7.3	**<80 IU/mL** (<50 HIV RNA copies/mL) plasma viral load at 36 weeks. For women with a history of previous delivery by C/S.	Vaginal birth after Caesarean section (VBAC) should be offered if appropriate.
10.7.4	**80-690 IU/mL** (50–399 HIV RNA copies/mL) plasma viral load at 36 weeks.	A planned caesarean section (PLCS) should be considered, following discussion with on call GUM consultant Tel: - switchboard on 90240503.
10.7.5	**≥690 IU/mL** (≥ 400 HIV RNA copies/mL) plasma viral load at 36 weeks.	PLCS is recommended between 38-39 weeks with steroid administration for fetal lung maturity as per NICE guidance.[21]

10.8 Recommended mode of birth for women presenting in labour NOT on HAART; on monotherapy; or if viral load >174,000 IU/mL (>100,000HIV RNA copies/mL). (Refer to BHIVA guidelines section 6.4 p40) [3]		**Mode of birth**
10.8.1	**DO NOT** delay delivery, if labour advancing.	**AVOID** vaginal delivery where at all possible.
10.8.2	Aim to deliver < 6 hours from ROM.	By caesarean section **TOP PRIORITY.**
10.8.3	Avoid invasive testing that may encourage maternal-fetal blood exposure (e.g. fetal scalp monitoring, fetal blood sampling).	If vaginal delivery is unavoidable.
10.8.4	If instrumental delivery is indicated.	Forceps is preferable to ventouse.

10.8.5	Contact: -RMDT: -Obstetric Consultant, GUM Consultant and Consultant Neonatologist / Paediatrician ASAP. Appendix 4. (Refer to BHIVA guidelines section 9.1.3, p81, or section 14.3 p38 of these guidelines, for HIGH RISK neonatal management). [3]
10.8.6	The following drugs should be commenced as per BHIVA guidelines section 6.4.3, p40 [3]:- • Intravenous Zidovudine should be given throughout labour and delivery at 2 mg/kg bodyweight given over one hour followed by a continuous intravenous infusion at 1 mg/kg/h until the umbilical cord is clamped. • Oral Nevirapine 200mg stat dose • Oral Raltegravir 400mg BD • Oral Lamivudine 150mg BD • Oral Zidovudine 300mg BD • Tenovofir 490mg stat dose (If pre-term) (The emergency drug pack is held on delivery suite).
10.8.7	If the mother is not on HAART 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.

10.9 Management of an unbooked woman admitted in labour / PROM (Refer to BHIVA guidelines section 6.4.3, p41) [3]		**Timescale**
10.9.1	Women presenting unbooked in labour / PROM, without a documented HIV result should be offered an urgent HIV test.	As soon as possible (ASAP).
10.9.2	With consent a 6 ml ETDA sample should be sent urgently to RVL using the “late booking in pregnancy” form.[11] RVL should be informed of the sample being sent and urgency of result.	Within 1 hour of admission.
10.9.3	The result should be available and a positive result will be phoned through to the ward by the RVL duty Virologist.	Within 4 hours of sample being sent.
10.9.4	If a result has not been communicated to the ward by RVL the result may be negative and can be accessed via the Belfast links labs. If result is not available RVL duty Virologist should be contacted Tel:-08889086946.	Within 4 hours of sample being sent.

10.10 Following receipt of a reactive HIV result for an unbooked woman in labour.		**Timescale**
10.10.1	A reactive/positive result must be acted upon immediately, with initiation of interventions to prevent MTCT of HIV without waiting for further/formal serological confirmation.	ASAP.
10.10.2	The HIV diagnosis should be given to the woman by the Consultant Obstetrician on call.	ASAP after result received.
10.10.3	Contact:-RMDT - Obstetric HIV Consultant, GUM HIV Consultant and neonatal team for advice on drug treatment and plan of care. (Refer to BHIVA guidelines section 9.1.3, p81, or section 14.3 p38 of these guidelines, for HIGH RISK neonatal management). [3]	ASAP.
10.10.4	Each Maternity Unit should hold an emergency HIV drug pack containing the maternal and neonatal drugs required. **Ensure this pack is regularly checked to ensure stock is intact and in date.** Clinicians should refer to MEDUSA injectable medicines guide for the preparation of the Zidovudine- (see Appendix 5, p50).	Ongoing.
10.10.5	The following drugs should be commenced: • Intravenous Zidovudine should be given throughout labour and delivery at 2 mg/kg bodyweight given over one hour followed by a continuous intravenous infusion at 1 mg/kg/h until the umbilical cord is clamped. • Oral Nevirapine 200mg stat dose • Oral Raltegravir 400mg BD • Oral Lamivudine 150mg BD • Oral Zidovudine 300mg BD. • Tenofovir 490mg stat dose (if pre- term).	ASAP after diagnosis has been given to the woman. (Do not delay treatment whilst contacting RMDT).
10.10.6	If the mother is not on HAART 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.	
10.10.7	2 X clotted blood samples should be sent for confirmation of HIV status to Regional Virology	ASAP.

	Lab using the late booking in pregnancy/confirmatory form.[11]	
10.10.8	Inform on call Paediatrician / Neonatologist and arrange for them to come and speak to the woman to discuss the implications for the baby, treatment and feeding recommendations.	ASAP either in labour if appropriate or as soon as possible after delivery.
10.10.9	**Delivery should be by emergency caesarean section (C/S)**	**ASAP.**

11.0 GUM responsibilities(The best clinical practice should be based on most up to date national guideline produced by BHIVA)[3]

11.1 Initial GUM review appointment		**Timescale**
11.1.1	All routine referrals of newly diagnosed HIV positive women identified during pregnancy should be seen by either the regional GUM team or the local GUM team if services available locally.	ASAP following diagnosis.
11.1.2	In early cases<20 weeks gestation.	Aim to have the initial consultation ideally within 2 weeks of diagnosis and no later than 24 weeks gestation.
11.1.3	For late cases ≥20 weeks gestation (not in labour).	Aim to facilitate the earliest possible consultation.
11.1.4	Women diagnosed in labour or immediately post-partum, or women who develop complications requiring urgent or immediate advice on management.	Should have immediate contact with a GUM consultant.
11.1.5	The MDT should discuss the following with the woman:- • The effect of HIV on the pregnancy. • The effect of the pregnancy on HIV. • Prevention of transmission to the baby. • Confidentiality and informing key health professionals. • Partner notification and testing of partner and other children.	At the initial consultation.

	• Drug therapy. • Family / social support. • Obstetric / antenatal care. • Mode of birth. • Infant feeding including recommendation of avoidance of breast feeding. • Postnatal care and assessing the status of the infant. • Psychological impact of HIV diagnosis.	
11.1.6	The woman should be encouraged to allow disclosure of her HIV status and care plan between all health care professionals involved in her care, including her General Practitioner (GP). The disadvantage and risk of potential medical error due to insufficiently shared information, risking both mother and baby, should be highlighted.	At the initial consultation.
11.1.7	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.	At the initial consultation.
11.1.8	The GUM team will assume the responsibility of partner notification and testing of other children (if relevant).	Following the initial consultation.
11.1.9	The woman's record of care (Appendix 6 p51) should be completed and a copy inserted into her GUM notes and her MHHR with her permission. This should be updated throughout pregnancy.	Following initial consultation.
11.1.10	Advice regarding the recommended mode of birth should be conveyed to the Obstetric Consultant later in pregnancy.	At the 36 week appointment.
11.1.11	Updates of management, especially when there are any changes, should be communicated to the woman's named consultant and the ANSC via a secure email. The information should be password protected.	Throughout pregnancy.

11.2 GUM investigations- (refer to BHIVA guidelines section 5.2)[3]	**Timescale**

11.2.1	Baseline clinical assessment of the woman should be performed: CD4 count, HIV viral load, HIV resistance testing, HIV and other baseline investigations.	At initial consultation.
11.2.2	Results of the above baseline investigations should be reviewed.	Prior to initiation of treatment, except for late - presenting women.
11.2.3	Consideration should also be given to screening for chickenpox immunity.	At initial consultation.
11.2.4	A full sexual health screening should be performed – this should include chlamydia; gonorrhoea; hepatitis B and C and syphilis screening, if not already performed as part of the antenatal screen.	At initial consultation.
11.2.5	The sexual health check should be repeated at a later stage of pregnancy if there are ongoing risks.	At any time in pregnancy when a risk is identified.
11.2.6	Other infections may be investigated based on clinical indications.	At initial consultation or anytime throughout pregnancy.
11.2.7	Monitoring investigations related to HAART (including FBP, U+E and LFTs) and virological responses should be performed.	Every 3-4 weeks following HAART initiation until complete suppression has been achieved.
11.2.8	The viral load should be monitored throughout pregnancy at 6-8 week intervals.	Once complete suppression has been achieved.
11.2.9	A viral load should be performed towards the end of pregnancy to facilitate the Obstetric Consultant's decision on mode of delivery.	Around 36-37 weeks gestation.

11.3 Maternal treatment (refer to BHIVA guidelines section 6.2, p38)[3]		**Timescale**
11.3.1	Women with a viral load >174,000 IU/mL (>100,000 HIV RNA copies/mL) and/or CD4 cell count less than 200 cells/mm^3 should be commenced on HAART.	Within the first trimester if possible.
11.3.2	All other women should be commenced on HAART.	As soon as possible in the second trimester and

		preferably before 24 weeks gestation.
11.3.3	Women with a history of genital herpes should be offered suppressive Acyclovir 400 mg three times daily, especially where a vaginal delivery is planned. This aims to reduce the risk of transmission of HIV infection, and to reduce HSV shedding and herpes recurrence at delivery.[22]	From 32 weeks gestation.
11.3.4	The woman should be reviewed postpartum – including assessment of viral load for potential resistance testing. HAART should be continued lifelong.	Around 3-4 weeks postpartum.

11.4 Infant Feeding discussion (refer to BHIVA guidelines section 9.4 p88) [3]		**Timescale**
11.4.1	Infant feeding should be discussed with the mother and although breastfeeding is not recommended she should be supported in her decisions and appropriate advice given regarding infant treatment and her ongoing risk factors following delivery.	Initial discussions can start at the initial consultation, but should continue later in pregnancy.
11.4.2	The leaflet "General information on infant feeding for women living with HIV" from BHIVA should be printed and given to the woman, or the on line link can be provided depending on the woman's wishes.[3]	Following discussion on infant feeding.

[22] https://www.bashh.org/guidelines

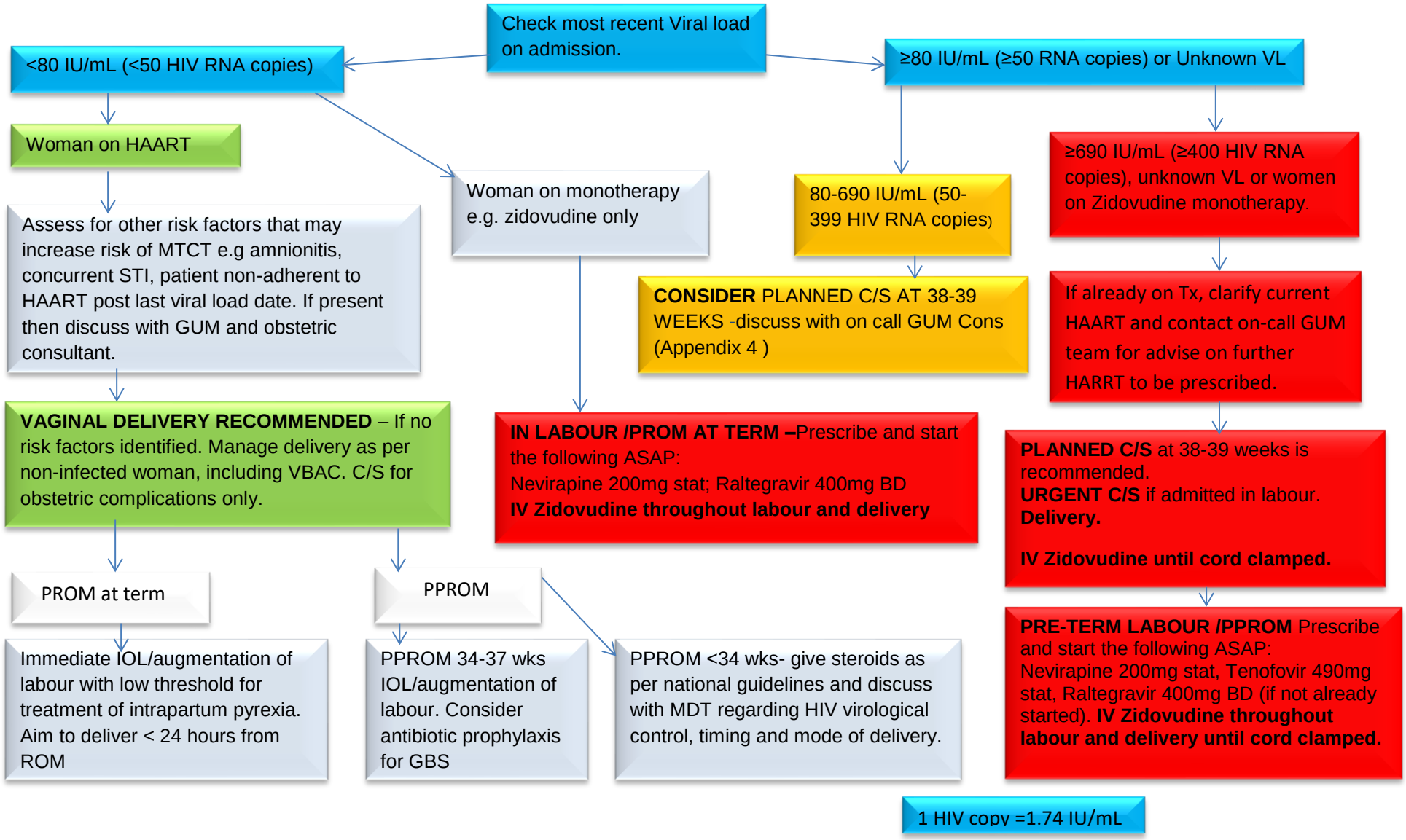
12.0 HAART drug interactions / side effects

- During the care of HIV positive 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. See link to website for up to date information.
  http://www.hiv-druginteractions.org/

- Help on such issues may also be sought from the HIV specialist pharmacist based in RVH. (See Appendix 4 p49 for contact details).

- Consultant Obstetricians and the GUM Consultants need to be aware that there can be potential overlapping presentations between adverse side effects of HAART treatment and complications of pregnancy, for example pre-eclampsia, cholestasis and other signs of liver dysfunction. Early liaison between Obstetric Consultant and GUM Consultants is important to avoid misdiagnosis.

Diagram1. Intrapartum management plan for HIV positive mothers. [3]



13.0 Neonatal management (refer to BHIVA guidelines section 9 p81) [3]

Good communication within the MDT and team working are vital to ensure proper management of the neonate.

13.1 Antenatal review		**Timescale**
	Arrangements should be made for an antenatal review of the woman with the Paediatrician who will be reviewing the baby postnatally so that neonatal management can be discussed.	Usually around 28-30 weeks.
	Details of the mother including edc, treatment, viral loads etc. should be uploaded onto the regional paediatric team shared drive for future reference in case queries arise at delivery. Trusts outside BHSCT will have to share this information with the regional team so that it can be uploaded.	Following the 28-30 week review.
13.2 Intrapartum preparation		
13.2.1	The Maternal care plan should be reviewed prior to making decisions about the neonatal management. It is important to check the current maternal HAART status and most recent viral load, as these will affect the choice of drug(s) to be used in the neonate.	When the mother is admitted either in labour, for induction of labour or planned caesarean section.
13.2.2	The MHHR 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.	When the mother is admitted either in labour, for induction of labour or planned caesarean section.
13.2.3	Note should be made of any other significant maternal issues e.g. need for interpreter services, substance misuse, psychosocial factors.	Prior to or following delivery.

13.3 Postnatal management		
13.3.1	The on-call Neonatal / Paediatric registrar should be informed.	Immediately after delivery.
13.3.2	The baby should be cleaned to remove any maternal blood.	Following delivery before transfer from labour ward.
13.3.3	Staff should adhere to universal precautions against infection, as with any babies. Refer to the regional infection prevention and control manual.[19]	When handling the baby
13.3.4	**Infant bloods**: -A 2ML EDTA sample of blood from the baby should be sent to the RVL using the specific "Congenital HIV Transmission" form (Appendix 9 p55). • Do **NOT** use a routine virology request form. • Do **NOT** use cord blood for new-born sample! • Use Category 3 green stickers on all samples and forms.	Following delivery prior to commencement of Anti Retro Viral treatment (ARV) in the baby.
13.3.5	**Maternal Blood:** A 5ML (2 purple topped bottles) sample of maternal whole blood in an EDTA bottle must also be sent along with the baby's sample on the "Maternal HIV assessment form" (Appendix 10 p56).	Within 4 hours of delivery.
13.3.6	Both samples should be sent to the: Regional Virus Laboratory, Kelvin Building, Royal Group of Hospitals Trust, Grosvenor Road, Belfast BT126BA Direct Tel: - 02890632662.	
13.3.7	The Neonatal / Paediatric registrar should commence the infant's post-exposure prophylaxis (PEP) as indicated in the neonatal care plan. If this is unavailable or unclear, advice from the Paediatric Infectious Diseases Consultant on call in RBHSC should be sought. (See Appendix 11 p57 for dosing recommendations).	Within 4 hours of birth.

13.3.8	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).	On diagnosis of abnormal clinical findings.
13.3.9	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 its' mother.	Following delivery.
13.3.10	Clinical status, growth and development should be monitored carefully at the baby clinic.	Following discharge.

14.0 Neonatal treatment- (refer to BHIVA guidelines section 9 p81) [3]

The following categories are used to determine the treatment of the neonate; very low risk; low risk and high risk. See below for explanation of each category and refer to the flow chart – (Appendix 7 p53).

14.1 VERY LOW RISK	
	At least two weeks zidovudine monotherapy is recommended if **ALL** the following criteria are met:- • mother has been on HAART for longer than 10 weeks. **AND** • has two documented HIV viral loads <80 IU/mL (<50 HIV RNA copies/mL) during pregnancy at least 4 weeks apart. **AND** • has an HIV viral load <80 IU/mL (<50 HIV RNA copies/Ml) at or after 36 weeks. **AND** • the initial infant HIV PCR is negative. **Treatment can be stopped at the next baby clinic review.**
14.2 LOW RISK	
	Extend to 4 weeks' zidovudine monotherapy: • if the criteria in 14.1 are not all fulfilled, but maternal HIV VL is <80 IU/mL (<50 HIV RNA copies/mL) at or after 36 weeks.

	• if baby born prematurely (<34 weeks), but most recent maternal HIV VL is <80 IU/mL (<50 HIV RNA copies/mL)
14.3 HIGH RISK	
14.3.1	**Give combination PEP for 4 weeks if:-** • maternal birth HIV VL known to be or likely to be >80 IU/mL (>50 HIV RNA copies/mL) on day of birth. • if uncertainty about recent maternal adherence to HAART. • if VL not known. • where the mother is found to be HIV infected only after delivery in cases of unbooked women and unplanned delivery. • where maternal HIV details are not available. • persistent maternal viraemia (high viral load) on HAART.
14.3.2	In the context of known maternal resistance to zidovudine in VERY LOW or LOW risk situations, zidovudine monotherapy is still recommended for infant PEP.
14.3.3	If HIGH RISK (combination PEP indicated) and there is a history of documented maternal zidovudine and/or nevirapine resistance, seek expert advice. If advice not immediately available, commence standard 3 drug PEP (zidovudine, lamivudine, nevirapine) until guidance is provided.

Neonatal PEP should be commenced very soon after birth, certainly within 4 hours.

The dose of Zidovudine depends on the baby's weight and gestational age. In sick infants or those unable to tolerate oral feeds, give IV Zidovudine. (Appendix 11 p57).

15.0 Neonatal discharge	
15.1	On discharge, mothers should be given written instructions on the following:- 1. Dose and volume to be given to the baby 2. Timings 3. Duration 4. What to do if the baby regurgitates or is sick 5. Where to get a further supply if the bottle breaks e.g. local trust, Pharmacy.
15.2	Discharge medication must be labelled by the pharmacy and where possible the mother counselled by a pharmacist.

15.3	The medicines for children leaflet should be given to the mother.[23]
15.4	A Paediatric review appointment should be made for 2 weeks either with the designated Neonatologist in RJMS or local Paediatrician depending on trust policy.
15.5	At the initial review appointment the Paediatrician should complete the Integrated Screening Outcomes Surveillance Service on line report.[24] Contact the ISOSS team to set up an account. Email: isoss@ucl.ac.uk

[23] https://www.medicinesforchildren.org.uk/sites/default/files/content-type/leaflet/pdf/Zidovudine%20for%20treatment%20of%20HIV%20infection.pdf

[24] https://www.isoss-online.org/

16.0 Infant feeding

In the UK and other resource rich settings the safest way to feed infants born to mothers with HIV is with formula milk, as this eliminates on-going risk of HIV exposure after birth. We therefore continue to recommend that women living with HIV feed their babies with formula milk. (BHIVA guidelines section 9.4.1 p88).[3]

Factors that increase the risk of HIV transmission via breast milk include:

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

HIV positive women should be advised against breastfeeding. However the woman's wishes should be respected and advice and support should be offered should she decide against recommendations to breastfeed.

16.1 Supporting women living with HIV to formula feed (BHIVA section 9.4.2 p89) [3]	
16.1.1	Abstaining from breastfeeding can have financial and psychological repercussions for women, requiring support from the HIV MDT.
16.1.2	Women advised not to breastfeed for their baby's health will be provided with free formula milk by GUM to minimise vertical transmission of HIV.

16.2 Supporting low risk HIV positive women who choose to breast feed against advice (BHIVA section 9.4.4 p90) [3]	
16.2.1	Information for women considering breastfeeding should be provided either in written form see attached leaflet from BHIVA or via web link depending on woman's wishes.[25]
16.2.2	Women should be fully informed about the ongoing risk of transmission of HIV through breastfeeding and the requirement for extra maternal and infant clinical monitoring.

[25] https://www.bhiva.org/pregnancy-guidelines (Breastfeeding information booklets 1&2)

16.2.3	Should they still decide to breastfeed they should be supported in their decision, if they fulfil the following criteria: • Have a fully suppressed HIV viral load (for as long a period as possible, but certainly during the last trimester of pregnancy) • Have a good adherence history • Have strong engagement with the perinatal MDT • Are prepared to attend for monthly clinic review and blood HIV viral load tests for themselves and their infant during and for 2 months after stopping breastfeeding (see BHIVA section 9.5.1.2 p91). [3]
16.2.4	Women who don't fulfil the above criteria and insist on breastfeeding should be referred to social care as this places their infant at significant risk of HIV infection.
16.2.5	A supportive and harm reduction approach of working openly together should be taken, to maintain trust and reduce the risk of women being pressurised to breastfeed in secret.
16.2.6	Maternal HAART (rather than an extended neonatal PEP) is advised to minimise HIV transmission through breastfeeding.
16.2.7	Since mixed feeding i.e. breast and bottle feeding or breast and solid feeding and the length of time a baby is breast fed increases the risk of transmission to the baby, women choosing to breast feed should be advised to exclusively breastfeed for the first 6 months only.
16.2.8	Women should be advised to cease breastfeeding if they develop any postnatal infection such as mastitis or if they or their infant has gastro-intestinal symptoms.
16.2.9	They should be given clear information, including how to manage common complications of breastfeeding, and have ready access to clinical advice and peer support. (Refer to BHIVA breastfeeding information leaflets 1 and 2).

17.0 Infant testing- (BHIVA guidelines section 9.5) [3]

A 2ml EDTA sample of blood from the baby should be sent to the RVL using the specific "Congenital HIV Transmission Follow Up" forms (Appendix 9 p55).

- Do **NOT** use a routine virology request form.
- Do **NOT** use cord blood for new-born sample!
- Use Category 3 green stickers on all samples and forms.

Timing of diagnostics for HIV infection is as follows: -

17.1 Testing for formula fed infants		**Timescale**
17.1.1	Prior to hospital discharge.	During the first 48 hours.
17.1.2	If HIGH RISK.	At 2 weeks of age.
17.1.3	Ongoing testing should be performed.	• At 6 weeks (or at least 2 weeks post cessation of infant prophylaxis) • At 12 weeks (or at least 8 weeks post cessation of infant prophylaxis) • On other occasions if additional risk.
17.1.4	HIV antibody testing for sero conversion should be checked.	At age 18–24 months.

17.2 Testing for breastfed infants		**Timescale**
17.2.1	Prior to hospital discharge.	During the first 48 hours.
17.2.2	Regardless of risk classification.	At 2 weeks of age.
17.2.3	For the duration of breastfeeding.	Monthly.
17.2.4	After cessation of breastfeeding.	At 4 and 8 weeks.
17.2.5	HIV antibody testing for sero conversion should be checked.	At age 18–24 months.

17.3 Other tests		**Comment**
17.3.1	Full blood count and platelets, U+E, glucose, creatinine, LFTs, 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.	Not routinely.

17.4 Diagnosis of infant	
17.4.1	HIV positive antibody testing in an infant aged less than 18 months indicates maternal infection, but does not diagnose infection in the infant.
17.4.2	If PCR continues to remain negative at 3 months there is a > 95% chance of an infant being **UNINFECTED**.
17.4.3	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. This may be due to covert breastfeeding, premastication of infant food or unknown interfamilial exposure.
17.4.4	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 18 months from birth two or more HIV antibody tests are negative.
17.4.5	If PCR is positive, repeat HIV tests immediately to confirm infection.
17.4.6	If the infant is shown to be *infected* (2 positive PCR) he/she should be referred promptly by phone to Dr Sharon Christie, Dr Paul Moriarty, or Dr Lynne Spiers, RBHSC.
17.4.7	In addition, both the mother and child should have urgent resistance testing performed.

18.0 **Prophylaxis for Pneumocystis Jirovecii Pneumonia (PCP)** (refer to BHIVA guidelines section 9.2 p87)[3]	
18.1	PCP prophylaxis is recommended from 1 month of age if the baby has a positive HIV RNA/DNA test at any stage or if the infant is confirmed to be diagnosed with HIV. This should only be stopped if HIV infection is subsequently excluded.
18.2	PCP prophylaxis should also 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 >1,740 IU/mL (> 1,000 RNA copies/ml) despite HAART.
18.3	There is no need to give routine PCP prophylaxis if maternal viral load is below the lower limit of detection at delivery.
18.4	Commence prophylaxis at 4 weeks of life, when anti-retroviral treatment is stopped.

18.5	Treat with Co-Trimoxazole, once per day orally, **3 times per week** (on Monday, Wednesday and Friday). (Appendix 11 p59).
18.6	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.

19.0	**Immunisations-** (refer to BHIVA Section 9.3 p87) [3]
19.1	Immunisations should be given as per national schedule.[26]
19.2	Rotavirus vaccine is not contraindicated (unless HIV diagnosis has been confirmed and the infant is severely immunosuppressed).
19.3	If there is VERY LOW or LOW risk of HIV transmission and BCG at birth is indicated, this should be given at the next review visit if initial HIV PCR is negative.
19.4	If HIGH risk of HIV transmission and BCG at birth is indicated– seek specialist advice.
19.5	The Unscheduled Immunisation Record form should be completed and copies should be sent to the Child Health System and the Health Visitor.

20.0 Neonatal management in maternal hepatitis co-infection-

(refer to BHIVA section 9.6 p93) [3]

All babies born in Northern Ireland will now receive hepatitis B vaccination at 2, 3 and 4 months along with the other childhood vaccines in the form of infanrix hexa, in line with National guidance.[27]

20.1 HIV and Hepatitis B co-infection		**Timescale**
20.1.1	Infants born to HIV positive women co-infected with hepatitis B should also receive selective immunisation, along with the universal vaccinations.	At birth (within 24 hours of delivery), 1 month, and 12 months of life.
20.1.2	Hepatitis B immunoglobulin (HBIG) should be given to the neonate at birth if:	Within 24 hours of delivery.

[26] https://www.gov.uk/government/collections/immunisation

[27] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/740421/Hexavalent_combination_vaccine_guidance_selective.pdf

	• Maternal HBV DNA concentration is >10^6 IU/mL • Maternal HBeAg is positive • Maternal Anti-HBe is negative • Maternal Anti-HBe is unknown • Baby is born weighing ≤1500g.	
20.1.3	HBIG can be given simultaneously with the vaccine but in a different site.	Within 24 hours of delivery.
20.1.4	Infants born to Hepatitis B positive mothers should be screened for HBsAg (to exclude infection) and HBsAb (to confirm response to vaccination). **These must be explicitly requested** on the virology request form (i.e. checking status of an immunised baby).	At 15-18 months.
20.2 HIV and hepatitis C co-infection		
20.2.1	Testing for HCV PCR is recommended for all infants born to mothers dually infected with HIV and hepatitis C (HIV/HCV).	At birth.
20.2.2	Repeat PCR testing for HCV RNA should be performed.	During the first year of life.
20.2.3	HCV antibody should be retested. (Antibody testing is unreliable until the infant is 15-18 months old).	At 18 months.

Appendix 1: - Trust generic email addresses

Trust	Generic email address
Belfast Trust (BHSCT)	DL-BTUrgentScreenResult@belfasttrust.hscni.net
Northern Trust (NHSCT)	AIS@northerntrust.hscni.net
South Eastern Trust (SEHSCT)	specialist.midwives@setrust.hscni.net
Southern Trust (SHSCT)	antenatal.results@southerntrust.hscni.net
Western trust (WHSCT)	antenatalinfection.screening@westerntrust.hscni.net

Appendix 2: - Antenatal GUM / RJMH transfer of care referral form for HIV positive mother. (To be completed by Consultant Obstetrician/ANSC)

<table>
<tr><td>ID label</td><td>Named consultant:-

Hospital of booking:-</td></tr>
<tr><td>Date of referral:-</td><td>Agreed EDC:-

Gestation today:-</td></tr>
<tr><td colspan="2">Known HIV infection:- Yes ☐ No ☐

Country and year of diagnosis:-

Current treatment:-</td></tr>
<tr><td>Previous obstetric history:-</td><td>Previous medical history:-</td></tr>
<tr><td>Current pregnancy details:-</td><td>Risk factors:-</td></tr>
<tr><td>Antenatal screening results:-

Hepatitis B Blood Group
Rubella Hb
Syphilis MSSU</td><td>Confirmatory bloods taken:-
Yes ☐ No ☐

Viral Load requested:-
Yes ☐ No ☐</td></tr>
<tr><td>Interpreter required:- Yes ☐ No ☐</td><td>Language spoken:-</td></tr>
<tr><td>Patient information leaflet given[28]

Yes ☐ No ☐</td><td>Transfer of care to RJMH criteria:-
Co-infection with Hep B or C ☐
Late booking (>30 wks) with high VL ☐
Other maternal /fetal indications ☐
Patient request ☐</td></tr>
<tr><td colspan="2">Consultant email address:- Tel:-

ANSC email address:- Tel:-

Signed:-</td></tr>
</table>

[28] http://www.aidsmap.com/translations

Appendix 3:- Antenatal management category 3

Addressograph Label

Positive status known / unknown prior to this pregnancy (delete as appropriate)

Diagnosis given or discussed by consultant _____date:

Family members who are aware of positive status- (comment below)

Partner: Siblings:

Parents: Others:

Do not discuss diagnosis when anyone present other that those named above

		Tick, sign & date
Given contact details for screening coordinator		
Consultation arranged with/or known to GUM		
Consent to inform GP		
Consent to inform community M/W and H/V		
Appointment to see paediatrician		
Discussion regarding breastfeeding contraindication		
GUM Formula Feeding project discussed		
Care plan for delivery in MHHR by 36 weeks		
GUM plan in notes by 36 weeks/latest viral load		
Social worker arranged by GUM - if required		

**delivery suite or operating theatre management – refer to woman's care plan/ trust policy*

Appendix 4: - Contact telephone numbers for the RMDT BHSCT.

Department	Name	In Hours	Name	Out of hours
Maternity Department	RJMS main reception	028 96151080		
Obstetrics	On-Call Labour Ward Consultant (sisters office no)	028 96150582		
GUM services RJMH	GUM Consultant secretaries	02896151034 / 51033 / 51036	On-Call GUM Consultant via switchboard	028 90240503
GUM services RJMH	Reception 9am-5pm	028 96151115		
GUM services RJMH	Nurse advice line	028 96151131		
GUM services RJMH	Health Advisor	028 96150535		
ANSC	BHSCT- Roberta Carlisle	07717696403		
Pharmacy	HIV Pharmacist	028 96150744	Mobile number for HIV pharmacist	079 177 98 310
Pharmacy	For drug supply - contact own Trust pharmacy /on call pharmacist first			
Pharmacy	BHSCT Pharmacy (for stock queries/supplies)	028 96150895	On-call pharmacist via switchboard.	028 9024 0503
Special care baby unit. RJMS reception	Dr Aoife McMorrow, Neonatologist	028 96156591	On-Call Neonatal Registrar (NICU number)	029 961 50 570
Belvoir ward (children's ID)	Dr Sharon Christie / Dr Paul Moriarty / Dr Lynne Spiers	028 96150346		
Regional Virology Laboratory	Duty Virologist	07889086946		

Appendix 5: - Preparation of Retrovir® (Zidovudine) IV Infusion

Zidovudine intravenous infusion is available as 10mg/mL vials. Each vial contains 20ml (200mg/20mL).

Zidovudine injection must be diluted before use.

Zidovudine injection must not be administered by IV Bolus injection or by rapid infusion.

Dilute with glucose 5% to a concentration of 2mg/mL as follows.

Prepare Retrovir® (Zidovudine) Infusion as follows:

- Use correct aseptic non-touch technique immediately prior to administration.
- Withdraw 100ml from a 500ml bag of glucose 5% and discard.
- Add 100ml (contents of 5 vials) of zidovudine 10mg/ml injection to the remainder of the 500ml bag of glucose 5%.
- Invert the bag several times to ensure even mixing.
- The prepared infusion contains 1g (1000mg) of zidovudine in 500ml, which gives a final concentration of 2mg/mL.
- If necessary a new infusion should be made after 24 hours.
- **NOTE:** Should the product appear cloudy either before or after dilution, or during infusion, the preparation should be discarded. If this happens a new preparation must be made to finish the dose.

References:

Summary of Product Characteristics Retrovir 10mg/ml IV for infusion - www.medicines.org.uk (accessed 27/9/19).

Medusa: Injectable medicines guide. Version 4.0 published 09/04/2010, accessed 27/09/19.

References: BHIVA Guideline: Management of HIV infection in pregnant women (2012). Prepared July 2012.

Appendix 6: - GUM record of care

Name:-	GUM number:-
DOB:-	Hospital Number:-
EDC:-	Gestation at booking:-

HIV Diagnosis:-

Positive pre-conception ☐ At booking <20 wks ☐

At booking > 20 wks ☐ Unbooked- diagnosed in labour / post delivery ☐

Baseline GUM results	Date	Result	Baseline GUM results	Date	Result
Viral load			STI screen GC / CT / N/A		
CD4			VDRL/TPPA		
Hep B status			Hepatitis C status		

Antiretroviral plan:

Patient already on HAART ☐	Regime:- Date started:-
Patient not on HAART ☐	Regime commenced: Date started:- Gestation:-

Comments:-

Signature:- Date:-

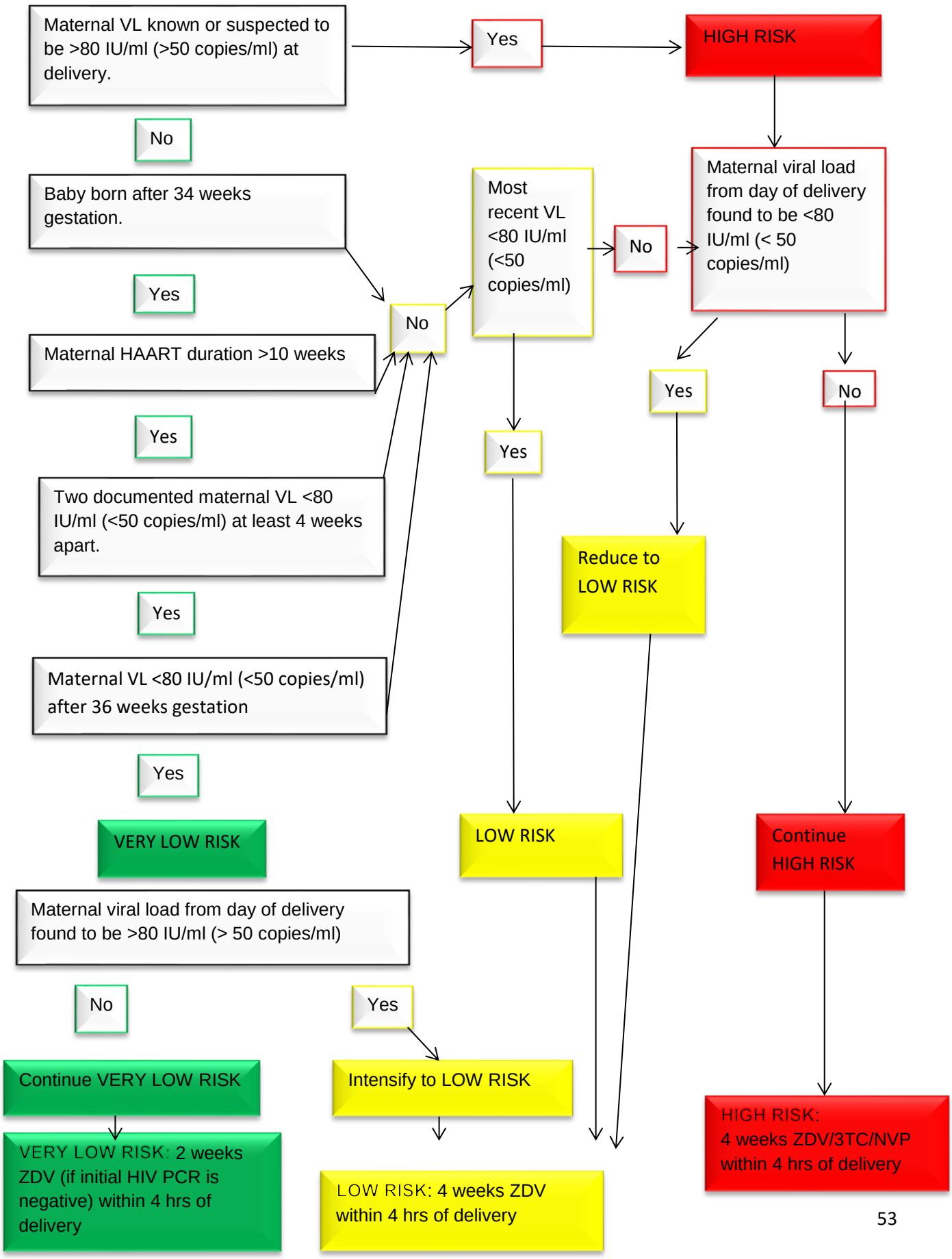
Review visits and follow up blood results

Date	Gestation	CD4 count	Viral Load	Comment	Signature

Extra comments at 3rd trimester review:-

Signature:- Date:-

Appendix 7: - Algorithm for infant treatment (BHIVA guidelines Figure 9.1 page 78)



Appendix 8: - Neonatal care plan

Mothers name / ID label	**Babies name / ID label**

Antenatal Care

Paediatric review antenatal around 28-30 weeks – (discuss treatment testing and infant feeding).

Signature:- Status:- Date:-

Postnatal care

Date of birth:-	Gestation at birth:-	Birth weight:-

Latest maternal viral load:-

Maternal adherence to HAART treatment:-

Maternal risk factors:-

Neonatal abnormalities detected:-

Venous blood sample (2ml ETDA) sent from the **baby** using the specific "Congenital HIV Transmission Follow Up" forms. (Appendix 9) **Do not use cord bloods!** ☐

Maternal blood (5ml EDTA) sent along with the baby's sample. (Appendices 9&10) ☐

Infant deemed to be:- (follow flow chart Appendix 7)

HIGH RISK ☐ → Baby to have 4 weeks ZDV/3TC/NVP

LOW RISK ☐ → Baby to have 4 wks ZDV

VERY LOW RISK ☐ → Baby to have 2 wks ZDV if initial HIV PCR Neg

Commence recommended neonatal ARV treatment within 4 hours of delivery.

Drugs commenced:-	Date and time first dose ARV given:-
Proposed method of infant feeding:-	Breast ☐ Formula ☐
2 week follow up appointment.	Date and time of appointment:-

Appendix 9: - Infant blood form

Send to: REGIONAL VIRUS LABORATORY, Kelvin Building, Royal Group of Hospitals Trust, Grosvenor Road, Belfast BT12 6BA. Direct Tel 028 96 155681 (9am-5pm Mon-Fri)

AFFIX LABEL OR ENTER DETAILS LEGIBLY

Forename/Initial	**Surname/Initial**	**D.O.B**	**Male/Female**
Mother's initials and DOB (or HPA sample reference number if known):		**Hospital No.**	
		Hospital	**Consultant /GP**
		Ward / Clinic	

NB: **Please send a contemporaneous sample of maternal blood (EDTA) using the separate "Mother's Sample" form at delivery**.

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 RECEPTION

2ml EDTA Blood from Child **Lab Code** {BHIC}

1. Leave as whole blood at 4°C - do NOT separate.
2. To be sent to PHE Colindale

Affix Category 3 sticker here

Specimen type EDTA blood	**Specimen Date & Time**	**Lab use**
Signature		

- **Take care that no blood contaminates the outside of the tube.**
- **Specimens should be packaged as per the laboratory user manual.**
- **Ensure specimen container lids are well secured to prevent leakage in transit.**

Appendix 10: - Maternal blood form

Revision Number	1.0	Document Number	M-2100
Author/Reviewer	AP Watt	Authoriser	T Curran
Active Date	06/10/20	Page Number	Page 56 of 61
Effective Date	06/10/20	Document Type	**Laboratory Form**
Maternal HIV Assessment			

Send to: REGIONAL VIRUS LABORATORY, Kelvin Building, Royal Group of Hospitals Trust, Grosvenor Road, Belfast BT12 6BA. Direct Tel 028 96 155681 (9am-5pm Mon-Fri)

AFFIX LABEL OR ENTER DETAILS LEGIBLY

Forename/Initial	**Surname/Initial**	**D.O.B**	**Male/Female**
Mother's initials and DOB (or HPA sample reference number if known):		**Hospital No.**	
		Hospital	**Consultant /GP**
		Ward / Clinic	

FOR THE WARD

During pregnancy - 5 ml EDTA Blood ☐

At Delivery - 5 ml EDTA Blood from Mother. ☐

FOR THE LABORATORY RECEPTION **Lab Code**

1. 5 ml EDTA Blood from Mother {BHIM}
2. Leave as whole blood at 4°C - do NOT separate.
3. To be sent to PHE Colindale

Specimen type EDTA blood	**Specimen Date & Time**	**Lab use**
Signature		

- **Take care that no blood contaminates the outside of the tube.**
- **Specimens should be packaged as per the laboratory user manual.**
- **Ensure specimen container lids are well secured to prevent leakage in transit.**

Appendix 11: - Doses of drugs commonly used in infants (BHIVA guidelines Appendix 3)**.**

<table>
<tr><th>DRUG</th><th>DOSE</th><th>COMMENTS/ SIDE EFFECTS</th></tr>
<tr><td colspan="3">NRTIs: Nucleoside Reverse Transcriptase Inhibitors</td></tr>
<tr><td>Zidovudine (ZDV) (Retrovir®)
Also known as azidothymidine (AZT)
Liquid – 10 mg/mL</td><td><u>Oral:</u>
<table><tr><th>Gestation +/- weight</th><th>Dose</th></tr><tr><td><30/40 gestation at birth</td><td>2mg/kg twice a day</td></tr><tr><td>30-34/40 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 the nearest 0.5 mg to assist administration</td></tr><tr><td>≥34/40 gestation at birth and >2kg</td><td>See dose banding table</td></tr></table><u>Duration oral dosing</u>:
• Very low risk monotherapy -2 weeks
• Low risk monotherapy - 4 weeks
• Combination therapy - 4 weeks
<u>Intravenous:</u>
• ≥34/40 gestation – 1.5mg/kg four times a day
• <34/40 gestation – 1.5mg/kg twice a day, change to four times a day at 34/40</td><td>Anaemia, neutropenia
<table><tr><th>Weight range (kg)</th><th>Oral dose - equivalent to 4mg/kg TWICE A DAY</th><th>Volume to be given orally 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>1.3 mL</td></tr><tr><td>3.26–3.50</td><td>14mg</td><td>1.4 mL</td></tr><tr><td>3.51–3.75</td><td>15mg</td><td>1.5 mL</td></tr><tr><td>3.76–4.00</td><td>16mg</td><td>1.6 mL</td></tr><tr><td>4.01–4.25</td><td>17mg</td><td>1.7 mL</td></tr><tr><td>4.26–4.50</td><td>18mg</td><td>1.8 mL</td></tr><tr><td>4.51–4.75</td><td>19mg</td><td>1.9 mL</td></tr><tr><td>4.76–5.00</td><td>20mg</td><td>2 mL</td></tr></table></td></tr>
<tr><td>Lamivudine(3TC) (Epivir®)
Liquid 10 mg/mL</td><td><u>Oral:</u> usually as part of combination therapy
2mg/kg BD – round dose <u>up</u> to nearest 0.5 mg to assist administration</td><td>Anaemia, neutropenia
(much less common than with ZDV</td></tr>
<tr><td>Abacavir (ABC) (Ziagen®)
Liquid 20mg/mL</td><td><u>Oral:</u> usually as part of combination therapy
2mg/kg BD– round dose <u>up</u> to nearest 1 mg to assist administration</td><td>Hypersensitivity reactions have not been noted in neonates</td></tr>
<tr><td>Tenofovir (TDF) (Viread®)
245mg tenofovir disoproxil = 300mg TDF</td><td><u>Oral:</u> usually as part of combination therapy
All doses now based on tenofovir disoproxil salt (TD)
(*245mg TD tablet dissolved in 24.5 mL water gives 10mg/mL)
4.9mg/kg (0.49 mL/kg*) OD –(round dose up to the nearest 0.5 mg (<10 mg) or 1 mg (≥10 mg) to assist administration)</td><td>Renal dysfunction: consider monitoring renal function weekly.</td></tr>
<tr><td colspan="3">Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)</td></tr>
</table>

<table>
<tr><td>Nevirapine (NVP)
(Viramune ®)
Liquid 10mg/mL</td><td><u>Oral:</u> usually as part of combination therapy
2 mg/kg once a day for 1 week, then 4 mg/kg once a day for 1 week – round doses <u>up</u> to the nearest 0.5 mg to assist administration.

If mother has already received >3 days of nevirapine: 4 mg/kg once a day – (round doses <u>up</u> to the nearest 0.5 mg)</td><td>Rash and liver dysfunction – rare in neonates.
Stop NVP after 2/52, in view of long half-life, continue other PEP agents for full 4/52.</td></tr>
<tr><td colspan="3">INSTI: Integrase Strand Transfer Inhibitor</td></tr>
<tr><td>Raltegravir
(RAL)
(Isentress®)
100 mg sachets for oral suspension (10mg/mL)</td><td><u>Oral:</u> usually as part of combination therapy

1.5 mg/kg once a day from birth to day 7, then 3 mg/kg twice a day until 4 weeks of age. See dose banding:

<table>
<tr><th>Body weight (kg)</th><th>Dose</th></tr>
<tr><td colspan="2">In full-term neonates>37 weeks</td></tr>
<tr><td colspan="2">Birth to 1 week- once a day dosing</td></tr>
<tr><td>2 to <3 kg</td><td>4 mg once a day</td></tr>
<tr><td>3 to <4 kg</td><td>5 mg once a day</td></tr>
<tr><td>4 to <5 kg</td><td>7 mg once a day</td></tr>
<tr><td colspan="2">1 to 4 weeks- twice a day dosing</td></tr>
<tr><td>2 to <3 kg</td><td>8 mg twice a day</td></tr>
<tr><td>3 to <4 kg</td><td>10 mg twice a day</td></tr>
<tr><td>4 to <5 kg</td><td>15 mg twice a day</td></tr>
</table></td><td>Rash and liver dysfunction: monitor liver function tests at 5–7 days of age.</td></tr>
<tr><td colspan="3">PI: Protease inhibitor</td></tr>
<tr><td>Lopinavir/ritonavir
(Kaletra ®)
Liquid:
5 mL = (Lopinavir 400 mg + ritonavir 100 mg)</td><td><u>Oral:</u> usually as part of combination therapy
300mg/m^2 (of lopinavir) twice a day – use dose banding table below

<table>
<tr><th>Weight range(kg)</th><th>SA range (m$^{2)}$</th><th>Kaletra dose</th></tr>
<tr><td>1–1.5</td><td>0.1–0.13</td><td>0.5 mL BD</td></tr>
<tr><td>1.51–2</td><td>0.14–0.16</td><td>0.6 mL BD</td></tr>
<tr><td>2.01–2.5</td><td>0.17–0.19</td><td>0.75 mL BD</td></tr>
<tr><td>2.51–3</td><td>0.20–0.21</td><td>0.8 mL BD</td></tr>
<tr><td>3.01–3.5</td><td>0.22–0.24</td><td>0.9 mL BD</td></tr>
<tr><td>3.51–4</td><td>0.25–0.26</td><td>1 mL BD</td></tr>
<tr><td>4.01–4.5</td><td>0.27–0.28</td><td>1.1 mL BD</td></tr>
<tr><td>4.51–5</td><td>0.29–0.30</td><td>1.2 mL BD</td></tr>
</table></td><td>Severe adrenal dysfunction, electrolyte imbalance and cardiogenic shock in neonates, especially premature infants.
Avoid in premature infants, only use, as per birth plan, when benefit of giving outweighs the potential risks.
Monitor for signs of toxicity, check U+E, pH, glucose, lactate, LFT, daily for first 5 days.</td></tr>
<tr><td colspan="3">FI: Fusion inhibitor</td></tr>
<tr><td>Enfuvirtide
(Fuzeon®)
(T-20)</td><td><u>Intravenous:</u> usually as part of combination therapy

2mg/kg IV every 12 hours (as infusion over 30 minutes)

Method: To reconstitute the 108mg vial slowly add 1.1 mL of water for injections from the vial of diluent provided to the vial of enfuvirtide powder, do not shake or invert the vial. The powder will take up to 45 minutes to dissolve. The resulting solution contains 90mg in 1 mL. Add 1 mL (90mg) of the solution to 10 mL of water for injections, then further dilute to 45 mL with water for injections, do not shake or invert the syringe. The final solution contains 90 mg in 45 mL (2 mg in 1 mL) from which to administer the required dose.</td><td>Experimental IV dosing regime

Use only, as per birth plan, when benefit of giving outweighs the potential risks</td></tr>
<tr><td colspan="3">PCP prophylaxis</td></tr>
<tr><td>Co-trimoxazole
(Septrin®)</td><td><u>BW ≥2kg</u> 120mg = 2.5 mL. <u>BW <2kg</u> 60mg = 1.25 mL

ONCE a day on 3 days per week</td><td>Only HIV infected infants, start at 4 weeks of age. May rarely cause rash and bone marrow suppression.</td></tr>
</table>

240 mg in 5 mL liquid		

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

Appendix 12:- Acknowledgements

Thank you to the following people for their contribution towards the development of this guideline:-

Name	Role	Trust
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Aine McDermott	ANSC	NHSCT
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Allison Wilson	ANSC	NHSCT
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